

EXHIBIT C

Neeraj Kohli, M.D.

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON
4

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6 IN RE: ETHICON, INC. * MASTER FILE NO.
7 PELVIC REPAIR SYSTEM * 2:21-MD-02327
8 PRODUCTS LIABILITY * MDL 237
9 LITIGATION *

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12 DEPOSITION OF NEERAJ KOHLI, M.D.
13 CROWNE PLAZA HOTEL
14 320 Washington Street
15 Boston, Massachusetts
16 March 21, 2016 1:13 p.m.

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20 Maryellen Coughlin, RPR/CRR
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1	I N D E X		
2	EXAMINATION		PAGE
3	BY MS. GUILFOYLE		6
4	BY MR. ORENT		162
5	BY MS. GUILFOYLE		168
6			
7	EXHIBITS		
8	NO.	DESCRIPTION	PAGE
9	1	Notice to take deposition of	7
10		Dr. Kohli	
11	2	Curriculum vitae of Dr. Kohli	19
12	3	Expert report of Dr. Kohli	23
13	4	Dr. N. Kohli Expert Report:	67
14		Internal Ethicon Documents Cited	
15	5	AUGS Position Statement on Mesh	74
16		Midurethral Slings for Stress	
17		Urinary Incontinence	
18	6	AUGS Frequently Asked Questions	96
19		by Providers Mid-urethral Slings	
20		for Stress Urinary Incontinence	
21	7	None	
22	8	None	
23	9	None	
24	10	Deposition of Dr. Kohli	102
25	11	Trial testimony of Dr. Kohli	102

Neeraj Kohli, M.D.

1	EXHIBITS CONTINUED		
2	NO.	DESCRIPTION	PAGE
3	12	AUA Guideline for the Surgical	112
4		Management of Female Stress	
5		Urinary Incontinence:	
6		2009 Update	
7	13	Effectiveness and complication	122
8		rates of tension-free vaginal	
9		tape-obturator in the treatment	
10		of female stress urinary	
11		incontinence in a medium- to	
12		long-term follow up Pan-Fen	
13		Tan, et al	
14	14	Seven years of objective and	125
15		subjective outcomes of	
16		transobturator vaginal tape:	
17		Why do tapes fail, Stavros	
18		Athanasίου, et al	
19	15	Five-year Results of a	131
20		Randomized Trial Comparing	
21		Retropubic and Transobturator	
22		Midurethral Slings for Stress	
23		Incontinence, Eija Laurikainen,	
24		et al	
25			

Neeraj Kohli, M.D.

1	EXHIBITS CONTINUED		
2	NO.	DESCRIPTION	PAGE
3	16	Medium-term and long-term	137
4		outcomes following placement of	
5		midurethral slings for stress	
6		urinary incontinence: a	
7		systematic review and	
8		metaanalysis, Giovanni A.	
9		Tommaselli, et al	
10	17	Two Routes of Transobturator	149
11		tape procedures in stress	
12		urinary incontinence: A	
13		meta-analysis with direct and	
14		indirect comparison of	
15		randomized trials, Pallavi M.	
16		Latthe, et al	
17	18	Long-Term Results of Burch	151
18		Colposuspension, Fuat Demirci,	
19		et al	
20			
21			
22			
23			
24			
25			

Neeraj Kohli, M.D.

1 P R O C E E D I N G S

2

3 NEERAJ KOHLI, M.D.,

4 having been first duly sworn, was examined

5 and testified as follows:

6

7 EXAMINATION

8 BY MS. GUILFOYLE:

9 Q. Good afternoon, Dr. Kohli.

10 A. Good afternoon.

11 Q. Am I pronouncing your name right?

12 A. Yes.

13 Q. As you know, my name is Kathy
14 Guilfoyle, and my associate John Veysey and I
15 represent -- well, are some of the attorneys that
16 represent the defendants in this case.

17 Could you please state your full
18 name and spell it for the record?

19 A. Neeraj Kohli. N-E-E-R-A-J, last
20 name Kohli, K-O-H-L-I.

21 Q. And am I correct, Dr. Kohli, that
22 you have been designated by the plaintiffs as an
23 expert on the topic of the TVT-O?

24 A. Yes.

25 Q. You understand that?

Neeraj Kohli, M.D.

1 A. Yes.

2 (Whereupon, Deposition Exhibit 1,
3 Notice to take deposition of Dr. Kohli,
4 was marked for identification.)

5 Q. (BY MS. GUILFOYLE) I'm going to
6 show you, sir, what's been marked as Exhibit 1
7 for this deposition and ask you to take a look at
8 it.

9 Now, I'm going to ask you specific
10 questions, but I guess my first question's
11 whether or not you have seen it before.

12 A. Yes, I was sent a copy of this just
13 recently.

14 Q. Okay. And looking at what's been
15 marked as -- I mean what's Schedule A on
16 Exhibit 1, have you had a chance to review that
17 before coming here today?

18 A. I didn't get a chance to review all
19 of it.

20 Q. Did you review at any of it?

21 A. Yeah, I looked at it very quickly
22 when I originally got it.

23 Q. Okay. I guess what I would like to
24 do is let me know whether or not you have any
25 documents either with you today or if not with

1 you today in your possession, custody or control
2 that are responsive to Schedule A.

3 A. Sure.

4 MR. ORENT: Hold on. Let me just
5 say, obviously we have some objections to some of
6 this material being produced. I don't think I
7 got this 'til mid last week, so we haven't had
8 the time to file a formal objection to certain
9 things on here, but we can deal with whether we
10 have objections based on --

11 MS. GUILFOYLE: Yeah, that's fine.
12 And in part the reason why the notice was late
13 was this whole issue of where this was going to
14 take place.

15 MR. ORENT: Yeah.

16 MS. GUILFOYLE: So fair enough.

17 A. Kathy, I can go through each of the
18 document requests or I can tell you what I
19 brought with me today.

20 Q. Oh, so you do have some stuff with
21 you?

22 A. Oh, I did, yeah.

23 Q. Okay.

24 A. I wanted to be prepared.

25 Q. First tell me what you have with

1 you today?

2 A. So I have a copy of my C.V.; I have
3 a copy of my Rule 26; and I have a thumb drive
4 which actually has the information that I was
5 provided by Motley Rice to review in preparation
6 for this case and the deposition.

7 Q. And is all of the information that
8 you were provided by Motley Rice to review in
9 conjunction with this deposition, is that all
10 reflected in your report?

11 A. Not all of it is reflected in the
12 report. Where I thought it was relevant it was
13 reflected.

14 Also in my report are experiences
15 that I've had, knowledge that I've gained in 20
16 years of doing this, as well as papers that I
17 have reviewed in the past or recently more in
18 conjunction with my teaching, my clinical
19 responsibilities and my knowledge in general.

20 Q. Okay. So can you tell me in
21 categories what type of information you were
22 provided by Motley Rice?

23 A. Sure. It's actually according to
24 the folders. I was provided certain past
25 depositions.

1 Q. Okay.

2 A. I was provided certain
3 documentations in terms of internal Ethicon
4 communications, whether they be e-mails or
5 reports.

6 I was also provided copies of IFUs,
7 patient education materials, anything else that
8 was for educational or promotional aspects, which
9 many of those I had already seen. I was provided
10 some references, some clinical references --

11 Q. Oh, go ahead, and I'll ask you.

12 A. -- in terms of articles which,
13 again, were generally articles that I'd seen
14 before but also other articles that I hadn't
15 seen, in addition to many of the articles that
16 I've looked at independently outside of this
17 litigation.

18 Q. Okay. You have with you a
19 computer; is that fair to say?

20 A. Yes.

21 Q. And are you reading from a list of
22 documents that --

23 A. The exact thumb drive that I've
24 actually given you is exactly these files, so I'm
25 just telling you exactly what I gave you. So I

1 have this for you.

2 Q. Oh, okay.

3 MR. ORENT: You know what I'd like
4 to do? I haven't had an opportunity to look at
5 it just to make sure that there's nothing
6 privileged on here, so I'll do that on a break --

7 MS. GUILFOYLE: That's fine.

8 MR. ORENT: -- so we can mark it as
9 an exhibit to the deposition.

10 MS. GUILFOYLE: Okay.

11 Had you finished going through the
12 categories of --

13 A. Yes.

14 Q. -- information that you've been
15 provided by Motley Rice?

16 Now, as far as past depositions, do
17 you recall what past depositions you were
18 provided?

19 A. So some -- so most of the -- some
20 of them I have read, and some of them I haven't,
21 but I was provided Dr. Weisberg's deposition,
22 Dr. Robinson's deposition, Dr. Owen's deposition,
23 Dr. Pinot Hinoul's deposition, and those are the
24 majority of the depositions that I reviewed.

25 Q. Were you provided other depositions

1 that you opted not to review?

2 A. I was provided them, but they were
3 not -- I didn't -- I wasn't provided them in a
4 timely enough manner to get them reviewed for
5 this deposition.

6 Q. Okay. So the four that you said,
7 Weisberg, Robinson, Owens and Hinoul --

8 A. Correct.

9 Q. -- are the four that you reviewed.
10 And were these depositions that you
11 specifically requested, or were they depositions
12 that were just given to you by Motley Rice?

13 MR. ORENT: Objection.

14 A. They were given to me.

15 Q. After reading the ones that were
16 given to you by Motley Rice, did you request
17 access to additional depositions?

18 A. No, the only other depositions I
19 had asked for were if there were any other
20 depositions for other experts for TVT-O, and so I
21 did get Dr. Shavari's TVT-O deposition, and I did
22 get Dr. Rosenzweig's and Dr. Blaivas.

23 Q. And did you get those depositions
24 prior to preparing your report?

25 A. No.

1 Q. So after you prepared your report?

2 A. Yes.

3 Q. Did you ask for them before you
4 prepared your report?

5 MR. ORENT: Objection.

6 A. No.

7 Q. As far as Ethicon documents, can
8 you estimate how many Ethicon documents you
9 reviewed?

10 A. In terms of number of documents --

11 Q. Yeah, yeah.

12 A. -- or pages?

13 Q. Well, either, whichever is easier
14 for you.

15 A. I would probably say it is close to
16 2000, 2500.

17 Q. Okay. And were these documents,
18 these Ethicon documents, again, documents that
19 were culled out and given to you as opposed to
20 documents that you specifically requested?

21 A. Correct.

22 Q. And after reviewing the documents
23 that were provided to you, did you obtain any
24 additional documents?

25 A. No.

1 Q. Did you request additional
2 documents?

3 A. No.

4 Q. Did you review all the documents,
5 Ethicon documents, that were provided to you?

6 A. Yes.

7 Q. And what was the general subject
8 matter of those documents?

9 A. I guess they would be in several
10 broad categories. One was e-mail correspondences
11 between Ethicon team members and either customers
12 or other team members. The other would be
13 internal reports. The other would be educational
14 or promotional or marketing materials. And that
15 would be the bulk of the documents that I
16 received.

17 Q. And were the documents that you
18 received, the Ethicon documents, were they during
19 a different specific time frame?

20 A. Most of them I would characterize
21 were from the early stages of development of
22 TVT-O to probably most recently would be changes
23 in the most recent IFU from 2015.

24 Q. Okay. And then you said you were
25 given certain patient education materials, did

1 you say?

2 A. Yes.

3 Q. And are you referring to like
4 brochures?

5 A. Exactly.

6 Q. And did you review brochures for a
7 certain time period?

8 A. I was given several brochures. I'm
9 not sure if I really paid attention to when they
10 were published or printed, but I reviewed any
11 brochures. And many of them I had already seen
12 because we used them in the past and we've seen
13 them as part of our patient educational
14 materials.

15 Q. Okay. And then you also said
16 clinical references. Are you referring to
17 studies?

18 A. Clinical studies, yes.

19 Q. And do you recall what studies you
20 reviewed?

21 A. Oh, there's a full variety of
22 different studies, and again, they are on the
23 thumb drive. Some of them were basic science
24 type regarding mesh. Some of them were clinical
25 comparative studies or observational studies

1 regarding surgical procedures ranging from TVT-O
2 to other surgical procedures. Some of them were
3 position statements or notices or directives from
4 professional societies. Again, a lot of that
5 clinical information was information that I had
6 already been exposed to in my general work
7 responsibilities, but they were provided to me in
8 a organized and more compact manner.

9 Q. Did you review all of those clinic
10 references in conjunction with coming up with in
11 your opinions that are set forth in your report.

12 A. I reviewed most of them. Some of
13 this were provided afterwards or I had seen some
14 papers afterwards, and those were not necessarily
15 added into my report.

16 Q. What do you mean by that, Doctor,
17 some you saw afterwards. Did you request ones
18 afterwards?

19 A. No, but in the course of us writing
20 the report, we're continuously reading the
21 literature, doing research, presenting papers,
22 teaching, so I've been exposed to those. But
23 again, I couldn't tell you exactly or
24 specifically which they were because I didn't
25 bring them into a file saying that this is part

1 of my knowledge base.

2 Q. And so those are papers that would
3 not be reflected on the thumb drive?

4 A. Correct.

5 Q. And when you say "us," when you're
6 talking about preparing the report, who are you
7 referring to?

8 A. Oh, just me. I'm sorry.

9 Q. Now, were there any other
10 categories of documents that we haven't gone
11 through?

12 A. No.

13 Q. And when were you retained in this
14 case, Doctor?

15 A. I think it was the latter half of
16 last year. Probably October, November.

17 Q. All right. Let's just finish out
18 Exhibit 1, if we can. So we've talked about the
19 thumb drive. I guess if we go through the
20 categories, we can just discuss whether or not
21 they were covered by what's on the thumb drive or
22 whether Mr. Orent has an objection or.

23 So it looks like number 1 would be
24 the -- category 1 would be the documents that are
25 referenced in the thumb drive?

1 A. Yes.

2 Q. All right. What about category 2?

3 A. I have not provided an invoice yet,
4 and I would have to go back and -- I haven't even
5 calculated the number of hours. A lot of this
6 was done in a fairly short time frame, while I
7 was doing other clinical responsibilities. So I
8 just got the work done, and now I have to go back
9 and do that. So I don't have necessarily a
10 invoice currently created or the exact number of
11 hours that I spent on the case.

12 Q. But do you have any ballpark number
13 of hours that you spent?

14 MR. ORENT: Don't guess. If you
15 have a reasonable approximation, you can give a
16 reasonable approximation.

17 A. I mean clearly it was greater than
18 100, but I don't know how many hours we spent.

19 Q. And the hundred, is that at your
20 hourly rate of -- is it a \$1000 an hour?

21 A. Yes.

22 Q. And how do you maintain your
23 billing records?

24 A. Oh, I -- well, I basically look at
25 how much time I've spent, and I basically write

1 down how much time I've spent on a calendar, and
2 then just basically go back and take a look at
3 all that, add up the time we've spent on
4 conversations and any other assorted time I've
5 spent on the case.

6 Q. So it's fair to say that this would
7 be something that would be easy enough for you to
8 do, to go back to your office and calculate the
9 total number?

10 MR. ORENT: Objection.

11 A. Well, I'm going to have to do it to
12 give them an invoice.

13 Q. Right.

14 A. You know, when I'm going to do it
15 and when I can get around to doing it, I can't
16 necessarily tell you that.

17 Q. Okay. Anyone else in your office
18 work on this case?

19 A. No.

20 (Whereupon, Deposition Exhibit 2,
21 Curriculum vitae of Dr. Kohli,
22 was marked for identification.)

23 Q. All right. Your curriculum vitae
24 I'll show you which has been marked as Exhibit 2.

25 Is that a fair and accurate copy of

1 your updated CV?

2 A. I think I have a more updated CV
3 which I brought with me.

4 Q. Okay.

5 A. Let me just make sure. Yes. So
6 this is a more updated CV, and I was going to use
7 this as a reference today, but I'd be happy to
8 give it to you or leave it with you afterwards.

9 Q. That's fine. If you could --
10 clearly when you were comparing what's been
11 marked as Exhibit 2 to the one that you brought
12 with you, you were looking for something to see
13 whether it was on the CV or not. Can you direct
14 me to the additional information that's on the
15 one in front of you and not on what's been marked
16 as Exhibit 2?

17 A. Oh, yeah. So I don't update my CV
18 as frequently as I should, but I won the Academy
19 Award in 2012.

20 Q. Oh, congratulations.

21 A. Thank you. So I knew that that was
22 there, on a more recent C.V., and I didn't see it
23 on yours. So that was one of the things that I
24 looked at, if it was there.

25 Q. So an Academy Award for what?

1 A. I was executive producer for best
2 documentary. Harvey Weinstein bought our film.

3 MR. ORENT: Wow.

4 MS. GUILFOYLE: Wow.

5 A. It was a good ride.

6 Q. What was the film?

7 A. It was called "Undefeated." It's
8 about a football -- underprivileged high school
9 football team in Manassas, Tennessee, and the
10 coach and the story.

11 Q. Oh, congratulations.

12 A. Thank you.

13 Q. Okay. Other than winning the
14 Academy Award, not to, you know, diminish that in
15 anyway, is there anything else --

16 A. Again --

17 Q. -- that you saw missing on the
18 version of the CV that I've marked as Exhibit 2?

19 A. Again, there's probably differences
20 between the two, and one of the reasons is that
21 every few years in terms of my Harvard academic
22 appointment I have to update my CV, and that's
23 really what brings me to update my CV. So I know
24 that I've added some things to this. But I just
25 knew that was not there, so that was one of the

1 things that was a red flag. But, again, I'm
2 happy to give you a copy of my updated CV.

3 Q. Any recent publications that you've
4 done on TVT-O?

5 A. Not recent, no.

6 Q. Do you know when the last date of
7 your publication on TVT-O was done?

8 A. I'm not even sure if we've really
9 done any specific publications on TVT-O. We have
10 done -- I have done review articles and grand
11 rounds about in general urogynecology, whether it
12 be surgical or non-surgical procedures, and it
13 may have been mentioned in that, but I can't
14 remember right off the top of my head if there
15 was a recent -- that we did any kind of recent
16 clinical paper specifically on TVT-O in a
17 singular or a comparative nature.

18 Q. Okay. So is it fair to say that
19 what's been marked as Exhibit 2 is generally a
20 fair and accurate representation of your resume?

21 A. In terms of TVT-O, yes.

22 Q. Right, okay. So let's look at
23 number 5.

24 A. So that is included -- oh, 5. 4 is
25 done.

1 Q. Right.

2 A. That is part of my expert report.

3 (Whereupon, Deposition Exhibit 3,

4 Expert report of Dr. Kohli,

5 was marked for identification.)

6 Q. (BY MS. GUILFOYLE) Okay. So your
7 expert report which actually I'll show you which
8 is marked as Exhibit 3.

9 A. Yes.

10 Q. And that's near the end of your
11 expert report you have a list of cases?

12 A. Correct.

13 Q. And is that a fair and accurate
14 representation of all the cases in which you've
15 given either deposition or trial testimony in the
16 past four years?

17 A. Yes.

18 Q. Okay. There are no cases missing
19 from that?

20 A. To my knowledge. I don't believe
21 so.

22 Q. Do you keep a list of cases in
23 which you've given trial or deposition testimony,
24 Doctor?

25 A. I don't. What I usually do is I

1 usually search my calendar, and usually it will
2 say trial or deposition, and that's what I
3 usually use.

4 Q. So if you were deposed, for
5 example, in 2015, you would remember that, right?

6 A. Right.

7 Q. And having reviewed the list of
8 cases, you believe that's fair and accurate?

9 A. I believe so, yes.

10 Q. What about number 7, graphics,
11 testing, recordings, spreadsheets?

12 A. I have none of those.

13 Q. Category 8?

14 A. I have none of those.

15 Q. And number 9, is it fair to say
16 that's what been marked as Exhibit 3 is a fair
17 and accurate copy of your final report?

18 A. It is.

19 Q. Category number 10?

20 A. I have none of those.

21 Q. Number 11?

22 A. Testing done by me. I have done no
23 testing.

24 Q. Okay.

25 A. Again, no testing for number 12.

1 Q. 13?

2 A. We have no plaintiff in this case.

3 Q. Right. 14, communications

4 reflecting.

5 A. I've had no communication with any
6 other experts.

7 Q. Okay.

8 A. Again, 15 --

9 Q. Right, is on the thumb drive.

10 A. Thumb drive.

11 Q. Okay.

12 A. 16, all of my opinions are
13 supported with the literature in reference on my
14 Rule 26.

15 Q. Okay. Do you have copies of any of
16 your deposition transcripts at your office or
17 elsewhere?

18 A. From previous trials?

19 Q. Right.

20 A. I do.

21 Q. Okay. And do you maintain those in
22 a certain file?

23 A. They're either maintained in a
24 certain file or they're part of a e-mail trail
25 with the lawyers. Some of them I --

1 MR. ORENT: Note my objection.

2 A. Some of them I got copies, and some
3 of them I didn't get copies of my depositions.

4 Q. Okay. How many times have you
5 testified, Doctor, at a deposition?

6 A. You mean taken a deposition?

7 Q. Been deposed, yeah.

8 A. I would say probably about 10 to 12
9 times.

10 Q. And of those 10 to 12 times, how
11 many of those occasions have been as an expert
12 witness?

13 A. I would say the vast majority of
14 them.

15 Q. And do you know the distinction I'm
16 drawing between like a treating physician and an
17 expert?

18 A. Yes. I was just about to say I
19 think one of the cases I was a treating
20 physician, maybe two of the cases. But I would
21 say probably, I would have to guess, between 9
22 and 10 of those would be as an expert.

23 Q. Okay. And in the cases where you
24 were a treating physician, is it fair to say that
25 you were not being deposed because you were a

1 defendant in the case?

2 A. Correct.

3 Q. Okay.

4 A. Touch wood.

5 Q. All right. And then what about
6 trial testimony, do you know how often you've
7 testified at trial?

8 A. I would have to guesstimate four or
9 five times.

10 Q. When's the most recent time you
11 have testified at trial, Doctor?

12 A. That probably would have been at
13 the Miklos case in Atlanta which is on my --

14 Q. Yes, it is on your --

15 A. -- Rule 26. And I think that was
16 probably two years ago, maybe. 2012, 2013.

17 Q. What was the Miklos case about?

18 A. The Miklos case was a med mal case
19 where the patient had a prolapse and Dr. Miklos
20 put in a mesh sacral colpopexy, and then she had
21 pain issues and recurrence afterwards, and she
22 brought a case against him regarding his
23 treatment.

24 Q. And you testified on behalf of
25 Dr. Miklos?

1 A. Correct.

2 Q. What was the product that was used
3 in that case?

4 A. Oh, I don't know which mesh he
5 used.

6 Q. Right.

7 A. I apologize. Again, it wasn't
8 focussed on the company or the actual product,
9 more on the diagnosis and treatment of the
10 condition.

11 Q. Sure. Fair enough. I just wanted
12 to know if you recalled.

13 What about 19?

14 A. No. Again, any graphics that I
15 used I included in my Rule 26.

16 Q. Okay. So the diagrams that you
17 have that are in there and stuff are what you're
18 referring to?

19 A. Correct.

20 Q. All right. 21?

21 A. I don't have any Ethicon products
22 that I used.

23 Q. 22?

24 A. Again, nothing relevant to this
25 case.

1 Q. Okay. 23?

2 A. I don't have any pending
3 publications or draft submissions currently, so
4 that would be not applicable.

5 Q. All right. 24?

6 A. Most of my presentations are all
7 included in my CV.

8 Q. Okay. Are there any ones that you
9 did relative to TVT-O that are not included in
10 your CV?

11 A. There may be some done many years
12 ago. Again, TVT-O is not a very contemporary
13 product in terms of my usage or education or
14 discussions currently. So I can't remember the
15 last time -- it would have been at least two
16 years is the last time where I've ever even
17 mentioned TVT-O in a presentation.

18 Q. Would there be some reason why,
19 Doctor, though, that you would include -- that
20 you wouldn't have included it on your CV?

21 A. Again, I give so many talks, and we
22 are so busy doing so many different things
23 that -- and the reality is after your CV is 50
24 pages, most people don't look at a lot of it.
25 And so given that we give so many grand rounds

1 and those kinds of talks, sometimes I don't
2 include every single talk that I've put in.

3 Q. Okay. And I guess my question
4 really is did you make a decision not to include
5 certain talks or presentations that you did with
6 respect to TVT-O on your CV?

7 A. No.

8 Q. All right. The next category,
9 communications to and from medical societies?

10 A. I don't have any communications.
11 25, I don't advertise my
12 availability as an expert or consultant in
13 litigation.

14 Syllabus and texts, number 26,
15 again, I don't have those available, but they
16 have not been relevant or germane to TVT-O.

17 Q. Okay. 27, is there anything other
18 than what's on the --

19 A. Correct, I've never given any prior
20 testimony, statements or presentations to any of
21 those organizations.

22 Q. Okay.

23 A. 28 is on the thumb drive.

24 Q. Okay. Is there anything that's not
25 on the thumb drive, Doctor, that is part of your

1 file in this case?

2 A. No.

3 Q. Okay.

4 A. And then --

5 Q. 29, you know, talks about
6 communications to and from counsel. And I guess
7 what I'm interested in knowing is whether you in
8 fact have communications to and from counsel that
9 obviously are not included on your thumb drive?

10 MR. ORENT: I'm going to object to
11 that. My understanding is that we've not given
12 any hypotheticals and that there are no facts or
13 assumptions underlying it, so that's in a
14 non-relevant category. And relative to
15 compensation, the Doctor has already testified
16 that he's yet to produce any bills, so there are
17 no documents responsive to that --

18 MS. GUILFOYLE: Okay. Well, let me
19 ask --

20 MR. ORENT: -- and so we object --

21 MS. GUILFOYLE: Okay.

22 MR. ORENT: -- to other documents.

23 Q. (BY MS. GUILFOYLE) Let me ask you,
24 Doctor, have you -- in conjunction with preparing
25 your report that's marked as Exhibit 3, did you

1 prepare drafts and exchange them with plaintiffs
2 counsel?

3 MR. ORENT: I'm going to instruct
4 him not to answer that question on the basis of
5 the Rule 26 as amended in December of 2010. I
6 think it's the 2010 amendments going forward make
7 that privileged.

8 Q. (BY MS. GUILFOYLE) Doctor, did you
9 prepare multiple drafts of the report?

10 A. No.

11 Q. You just prepared one draft?

12 A. And there were -- I think there
13 were some typos and some verbiage that was just
14 revised because, more for typo, but there was no
15 material changes in my Rule 26.

16 Q. Okay. And did you have an
17 understanding as to what categories needed to be
18 addressed in the Rule 26 disclosure --

19 MR. ORENT: Objection.

20 Q. -- or what was expected to be
21 contained in the report?

22 MS. GUILFOYLE: I'm asking him
23 personally.

24 MR. ORENT: Okay. So you can
25 answer with respect to your understanding but not

1 the substance of communications with counsel.

2 So, in other words, you should not
3 repeat conversations you've had, but you can give
4 your understanding as to what was suppose to be
5 in the report.

6 A. So I was instructed or counseled
7 that what my opinions were about TVT-O and how
8 the procedure was is what I should concentrate
9 on, and so all of the opinions that I have in my
10 Rule 26 were all my opinions of what I felt TVT-O
11 was --

12 Q. Okay.

13 A. -- and then data that supported
14 those opinions.

15 Q. And then short of just changing
16 some verbiage and typos, you never made any
17 changes once you drafted the initial report; is
18 that your testimony?

19 A. Correct.

20 Q. Can you briefly just describe for
21 me your formal educational background?

22 A. Yes. I completed high school in
23 Holliston High School, 1985. When you're an
24 Indian male, you have a choice of becoming an
25 engineer or a doctor. My father was an engineer.

1 My grandfather was a doctor. I thought I looked
2 good in white, so out of high school I decided I
3 wanted to be a doctor, and I got admitted into
4 the six-year med program at BU. I did my
5 undergrad in two years. I had a guaranteed
6 admission into med school right out of high
7 school, and then I did my medical school at
8 Boston University.

9 Following that applied to different
10 areas for residency. I've always kind of been a
11 family oriented person and decided to stay in
12 Boston and did my four-year residency at Beth
13 Israel Hospital in Boston affiliated with Harvard
14 Medical School.

15 During that time period, I had the
16 privilege of working with David Staskin who is a
17 world renowned female urologist who said that
18 you've good hands, don't waste them, and the next
19 thing I knew I entered the fellowship of
20 urogynecology at Mickey Karram. It was the one
21 place that I interviewed because it was a last
22 minute decision, and I was privileged enough to
23 spend two years with Mickey. I learned a lot.
24 He offered me the opportunity to stay on with him
25 as a partner, which I did for about a year and a

1 half.

2 At one point I started thinking
3 maybe I'll stay here, and we started looking for
4 houses, or I started looking for houses. And in
5 Cincinnati if you want to have a nice house, you
6 live on the Kentucky side so you can see
7 Cincinnati. And when my friends in the northeast
8 realized I might actually be moving to Kentucky,
9 they gave me a lot of flak, and then I decided to
10 come back to Boston.

11 I came back, and I joined Peter
12 Rosenblatt at Mount Auburn Hospital. At that
13 time, many urogynecologists were leaving Boston,
14 and so even though we were at Mount Auburn
15 Hospital, I had the opportunity to provide urogyn
16 services to Tufts New England Medical Center and
17 Beth Israel, and I was co-division chief of both
18 of those areas.

19 During the six-year program, I
20 double majored in economics and premed, so I
21 always wanted to do my MBA. So I did the
22 executive MBA program at Kellogg. I did that for
23 two years while I was still practicing. And as
24 soon as I finished, six months following that the
25 Brigham & Women's called me up and said we're

1 looking for a new division chief, and we'd like
2 you to throw your name in the hat. I applied for
3 that position, was privileged to get that
4 position. So I started the division as well as
5 the fellowship at Brigham & Women's. I was there
6 for seven to eight years. We built up one of the
7 busiest urogyn divisions in the country. I
8 continued to train fellows, had a great time.

9 And my father had passed away
10 during that time period, and I decided that I
11 wanted to have a better work life balance, and I
12 wanted to pursue some more entrepreneurial
13 activities, so I resigned my position at the
14 Brigham at that time while maintaining my Harvard
15 academic affiliation.

16 I'm currently in private practice
17 as medical director for Boston Urogyn, but it
18 allows me more time to spend with my family as
19 well as more time to do some of these other
20 entrepreneurial activities.

21 Q. Okay. Thank you, Doctor.

22 A. You're welcome.

23 Q. So you are board certified in what
24 areas?

25 A. Ob-gyn and female reconstructive

1 pelvic surgery.

2 Q. Do you currently implant mesh?

3 A. Yes.

4 Q. And when did you first start to
5 implant mesh?

6 A. That would probably be during my
7 training.

8 Q. Okay. As a resident?

9 A. As a resident, we would do some
10 slings. The traditional techniques of slings
11 because minimally invasive midurethral slings
12 weren't there then.

13 Q. Okay.

14 A. But also during my fellowship we
15 did a lot of sacral colpopexies as an open
16 approach, so we did implant mesh during that time
17 period as well.

18 Q. Do you currently implant any
19 midurethral slings?

20 A. Yes.

21 Q. Do you -- what type of slings do
22 you implant?

23 A. Although I have done many in the
24 past, currently we do only retropubic suburethral
25 slings.

1 Q. And how long have you been --
2 limited your sling practice to retropubic?

3 A. I would have to guess. Probably
4 the last five, six years.

5 Q. And is there a particular
6 manufacturer or brand sling that you implant?

7 A. We currently use the Gynecare TVT
8 at one of our hospitals, and I use the Boston
9 Scientific Prolift -- I'm sorry. Advantage Fit
10 at one of our other hospitals.

11 Q. And how many times per month or per
12 year if it's easier would you estimate you
13 implant a suburethral sling?

14 A. I'm probably doing anywhere from 15
15 to 25 slings a month.

16 Q. And that would be any combination
17 of those two manufacturers?

18 A. Yes.

19 Q. And those slings are both made out
20 of polypropylene mesh, correct?

21 MR. ORENT: Objection.

22 A. Yes.

23 Q. Was there a certain period of time,
24 Doctor, if any, when you implanted the TVT-O?

25 A. Yes.

1 Q. Okay. And during what time frame
2 did you implant the TVT-O for?

3 A. I think we -- and again, this is
4 just based on my recollection. The first two or
5 three years after TVT-O was introduced, which I
6 believe was in 2003, 2004, we were implanting
7 TVT-O at that point and then stopped thereafter.

8 Q. So roughly 2003, 2004 to 2006?

9 A. Yeah, 2005, 2006.

10 Q. And when you were implanting the
11 TVT-O sling, do you have an estimate as to how
12 many times per month on average you implanted
13 that sling?

14 A. I don't have an estimate on how
15 many times per month, but I would say that I've
16 probably done between 50 and 100 TVT-O slings.

17 Q. Total?

18 A. Total.

19 Q. And do you record that information
20 anywhere? Would that be something that you could
21 go back and look at to get the exact number or
22 not?

23 A. So one of the problems has been is
24 that in the last 15 years I've gone from one
25 hospital system to another to another, and

1 oftentimes we -- in those days we were using
2 Outlook which tended to be hospital specific.

3 Q. Mm-hmm.

4 A. And I didn't have the foresight to
5 say that when I'm leaving the hospital I'm going
6 to download all of my e-mails and all of my
7 calendar data which was in Outlook. So I have
8 lost access to many of those.

9 Now as we go to a cloud-based
10 system, it's a little easier to keep those, but
11 unfortunately, I don't have access to that data
12 which would still be in a previous institution.

13 Q. Sure. Now, I'm not saying, Doctor,
14 that you should or you shouldn't have it. What
15 I'm asking you really is whether you do have
16 access to that?

17 A. I don't.

18 Q. Okay. And of those 50 to 100
19 people that you implanted the TVT-O, how many, if
20 you can recall, had complications?

21 A. What do you mean by complications?
22 In terms of intraop --

23 Q. Complications that you
24 attributed --

25 A. -- postoperatively --

1 Q. Yeah, postoperatively that you
2 attributed to the TVT-O sling.

3 MR. ORENT: Objection, form.

4 A. It's hard for me to recall that
5 number right now off the top of my head.

6 Q. How about a ballpark number?

7 MR. ORENT: Objection. If you can
8 provide a reasonable approximation, you can do so
9 but don't guess.

10 A. Yeah, I would really be guessing
11 given the number of the many procedures we were
12 doing during that time period, different types of
13 slings, different products of slings. So it
14 would be really a guess for me to say how many
15 complications we had during that time period.

16 Q. Okay. So there's no way that you
17 could go back and recreate that information?

18 A. No.

19 Q. All right. During that time frame
20 when you were implanting the TVT-O sling, were
21 you implanting other slings as well?

22 A. Yes.

23 Q. And what other slings were you
24 implanting at the same time?

25 A. Again, we were doing retropubic

1 slings --

2 Q. Mm-hmm.

3 A. -- and we were doing transobturator
4 slings outside in.

5 Q. So which manufacturer were you
6 using?

7 A. During that time period because we
8 were at multiple hospitals, we would always use
9 different manufacturers so that the residents and
10 the fellows could get good experience and then we
11 could also have good experience.

12 So in the past, we've used various
13 manufacturers. It's hard for me to remember
14 exactly during that time frame which
15 manufacturers. But in the past we've used
16 Coloplast, we've used AMS --

17 Q. That's like the SPARC sling?

18 A. No, the AMS Monarc sling.

19 Q. Oh, the AMS Monarc, okay.

20 A. We've used a Bard sling. Again,
21 you asked specifically about the TOT.

22 Q. Right.

23 A. We used Gynecare, and we used
24 Kildare. As well as the Boston Scientific.

25 Q. And what was that?

1 A. I think that's called the Lynx.

2 Q. Lynx?

3 A. Again, all of these were
4 transobturator outside in.

5 MR. ORENT: I think it's the
6 Obtryx.

7 THE WITNESS: It was Obtryx, yes.
8 Lynx is another one. It's a prepubic.

9 Q. And when you say "we," are you
10 referring to your practice?

11 A. It's me, my fellows, my residents.

12 Q. Okay. So when you're talking about
13 the numbers, you're referring to your group
14 collectively or are you referring to you,
15 yourself?

16 A. Me as the surgeon.

17 Q. Okay. So the 50 to 100 TVT-O was
18 you, not your group?

19 A. Yes.

20 Q. What about your group, do you have
21 a sense of how many TVT-Os your group implanted?

22 MR. ORENT: Objection.

23 A. I don't. I never keep a track of
24 what my partner or partners were doing and what
25 cases they're doing.

1 Q. And what was the reason, Doctor,
2 that you stopped using the TVT-O sling, if there
3 was a specific reason?

4 A. I felt it was not as safe as some
5 of the other transobturator techniques.

6 Q. And why is that?

7 A. Well, I did a lot of training for
8 Gynecare during that time period, and one of the
9 things that really left a mark on me is we did a
10 cadaver lab at Newton-Wellesley Hospital --

11 Q. Yeah.

12 A. -- and May Wakamatsu who was the
13 chief of urogynecology at MGH was one of the
14 participants.

15 Q. Right.

16 A. Now, here's a woman who has a lot
17 of knowledge of the anatomy, has a lot of
18 experience doing surgical procedures for
19 incontinence, and I remember vividly that I was
20 teaching her at my cadaveric station, and she put
21 the needle in, and she turned the handle parallel
22 to the floor, and when she advanced the needle,
23 it came out retropubically. And at that point I
24 realized training other doctors on this technique
25 was complicated and complex and could cause

1 complications.

2 In addition, my continued knowledge
3 of the procedures really told me in my experience
4 that I thought the outside in was safer.

5 Q. Okay. Did you have any trouble
6 using the TVT-O sling when you were implanting
7 it, Doctor?

8 A. To my recollection, I don't
9 remember any obvious complication, but if I felt
10 like it was a risky procedure and there was a
11 safer alternative, in the best interests of my
12 patients I didn't feel like I could continue
13 using it.

14 In addition, I had a discussion
15 with Gynecare during that time period because all
16 the other companies had a transobturator
17 outside-in approach, and I felt like Gynecare's
18 discussions with me about why the inside-out
19 approach was better didn't seem valid in my mind,
20 and for those reasons we stopped using the
21 product.

22 Q. Now, are the discussions that
23 you're referring to set forth in your Rule 26
24 report?

25 A. They are.

1 Q. Did you have any other discussions
2 other than what's set forth in your Rule 26
3 report with Gynecare with respect to the TVT-O?

4 A. No, that was -- they're fully
5 reflected in my Rule 26.

6 Q. So no further discussions?

7 A. Not to my recollection.

8 Q. Well, do you have any reason to
9 believe, Doctor, that you had other discussions
10 but they're not reflected in your report?

11 A. No.

12 Q. At a certain point in time, did you
13 stop -- well, strike that.

14 At a certain point in time, did you
15 do preceptor training for Ethicon or Gynecare?

16 A. Yes.

17 Q. And during what time frame did you
18 do that?

19 A. We were very active doing training
20 from the initial introduction of Gynecare TVT all
21 the way to TVT-O and then stopped or reduced our
22 activities with Gynecare about that time and as
23 Prolift was coming out.

24 Q. Did you do any preceptor training
25 for Prolift?

1 A. I don't recall whether we did. I
2 don't think so.

3 Q. Okay. Did your position with
4 respect to the TVT-O sling, was that impacted in
5 any way with the decision not to have as much
6 training you set forth in your report?

7 MR. ORENT: Objection to form.

8 Q. Yeah, that is a bad question.

9 In your report, Doctor, I note that
10 you make a reference to a decrease in training by
11 Ethicon and a reference to an increased amount of
12 training by sales reps. Do you recall that in
13 your report?

14 A. Yes.

15 Q. Did your opinion as to the safety
16 and efficacy of the TVT-O sling change as a
17 result of Ethicon or Gynecare's change in
18 training?

19 A. Well, I felt like the TVT-O was not
20 a safe procedure. One because of the
21 instrumentation, two because of the anatomic
22 procedural content, and then three also because
23 of the educational program.

24 Q. But at a certain point in time,
25 Doctor, you implanted between 50 to 100 TVT-O

1 slings, correct?

2 A. Yes.

3 Q. I'm trying to figure out what was
4 it that all of a sudden made you decide I'm not
5 going to use it anymore.

6 MR. ORENT: Objection, asked and
7 answered.

8 A. And, again, I think I answered that
9 question. It was a combination of doing the
10 cadaver lab and seeing how complicated the
11 instrumentation was, seeing that the anatomy and
12 how the procedure was being done in relationship
13 to the anatomy was not as safe as the
14 alternatives, as well --

15 Q. What do you base that on?

16 A. Based on my knowledge of the
17 anatomy and some of the things that I did talk
18 about in the TVT-O report as well as subsequent
19 papers that have come around in talking about
20 anatomic relations and what the risk structures
21 are in that space.

22 Q. As far as the --

23 MR. ORENT: Hold on. Were you done
24 with the answer to that question?

25 THE WITNESS: Yes.

1 Q. As far as the complaint made by or
2 your observation with respect to the cadaver lab
3 at Newton-Wellesley, was that the only
4 observation that you made that caused you concern
5 about the TVT-O?

6 A. No, I think that was a very vivid
7 memory --

8 Q. Okay.

9 A. -- and I think it really stuck with
10 me given who it was and what we were seeing. But
11 I have had the opportunity to see hundreds of
12 physicians in cadaver labs as well as during our
13 surgical preceptorships and what their knowledge
14 base is and the kinds of questions that they ask,
15 and I just felt as a combination of many of those
16 things TVT-O was not a very applicable product to
17 the broad generally trained gynecologist, and I
18 just felt that it was not a very safe product in
19 relationships to the other products that were
20 available.

21 Q. That's your personal opinion?

22 MR. ORENT: Objection.

23 A. Correct.

24 Q. Do you know whether the doctor at
25 Mass. General, for example, went on and implanted

1 a TVT-O sling?

2 A. I don't.

3 Q. Did any doctors that you did any
4 training with at the cadaver lab or otherwise
5 with the TVT-O ever voice any concerns to you
6 about it?

7 A. I remember in the group that we
8 were at -- and again, I don't know which doctors
9 were in that group -- many of them that was a
10 little scary to them about where the needle came
11 out and where it should have come out, so I do
12 remember that. Again, I just don't have the
13 details on who those doctors were.

14 Q. But it's fair to say, Doctor, with
15 any new procedure there's always some
16 apprehension about how it works, and how
17 successful it will be; is that fair to say?

18 MR. ORENT: Objection.

19 A. Yes.

20 Q. So you can't tell me today that
21 these concerns that you just voiced were nothing
22 more than that, can you?

23 MR. ORENT: Objection, misstates
24 his prior testimony.

25 A. Repeat the question for me.

1 Q. Sure. Do you need the prior
2 question?

3 A. No.

4 Q. Okay. You can't tell me that the
5 comments or apprehensions that -- the comments
6 that they made were anything other than the
7 apprehension felt with a new procedure or a new
8 product?

9 MR. ORENT: Objection.

10 A. Correct. Part of it was me, my
11 apprehension as somebody who had been a surgical
12 preceptor for over a thousand physicians in the
13 past and seen how they did these procedures for
14 the first time or the second time in the cadaver
15 lab and how they were doing this procedure in a
16 comparative fashion.

17 Q. When did you stop using the TVT-O
18 in relationship to when you stopped receiving
19 compensation for being a preceptor?

20 MR. ORENT: Objection.

21 A. I don't think there was a
22 correlation to that. And, in fact, part of it
23 was is that up 'til then we had, me and a few
24 other physicians, had been the core team where
25 all Gynecare technology was being discussed,

1 developed, trialed, researched, taught, and so I
2 know that there was talk of us also being
3 involved in the Prolift and being involved in the
4 teaching and training of that procedure, but that
5 was another procedure that I didn't feel
6 comfortable with. So it wasn't the availability
7 of compensation or teaching opportunities. It
8 was more my own apprehension and anxiety about
9 the procedures.

10 Q. Okay. Did you -- but it's fair to
11 say that you stopped receiving compensation from
12 Ethicon and Gynecare?

13 A. Well, when I stopped using the
14 product, there was no preceptorships to be done
15 if I wasn't using the product, so that is a true
16 statement.

17 Q. Okay. Is it your testimony that
18 because you decided to stop using the product
19 that was why you stopped being retained as a
20 preceptor or hired as a preceptor?

21 MR. ORENT: Objection.

22 A. Yes.

23 Q. Do you agree that one of the goals
24 of a urogynecologist is to advance the care of
25 women?

1 MR. ORENT: Objection.

2 A. I think that's a very vague
3 question, and the reason being is that not all
4 advancements are good, safe or effective. I
5 think some advancements are better for patients
6 in terms of safety, efficacy outcomes, and there
7 are some advancements that aren't, and I think
8 part of our job as clinicians is to do what's
9 best for our patients and do no harm and be
10 critical about technology and advancements in
11 medicine, and sometimes wait for appropriate data
12 before we decide to either go further or to adopt
13 or not adopt any advancement that's proposed.

14 Q. Did you ever participate in any
15 clinical trials for the TVT-O?

16 A. I can't remember, and I don't think
17 we did.

18 Q. I certainly will defer to you to
19 look at your resume. I can tell you that I did
20 not see any mention of that.

21 A. Yeah, I don't think we did any
22 clinical trials of the TVT-O.

23 Q. Okay. Did you ever participate in
24 any peer-reviewed studies on the use of the
25 TVT-O?

1 A. Let's see here. I don't believe we
2 did. Yeah, I don't think we've written, again,
3 any peer-reviewed studies analyzing the TVT-O.

4 Q. Are you familiar with other studies
5 that have been peer reviewed analyzing the TVT-O?

6 A. Yes.

7 Q. Are you familiar with other studies
8 involving like mata-analyses?

9 A. Yes.

10 Q. Do you know what the term
11 mata-analyses means?

12 A. Meta-analyses?

13 Q. Meta.

14 A. Yes.

15 Q. What does that mean, Doctor?

16 A. It essentially means looking at a
17 series of different papers that have been done
18 and pooling that data and doing an analysis of
19 that data in order to increase sample size as
20 well as the number of operators or physicians
21 presenting that data.

22 Q. And do you rely on those in your
23 practice, Doctor?

24 A. We rely on a variety of
25 information, clinical research, meta-analyses,

1 personal experience, but that would be one of the
2 components of something we would look at in terms
3 of data?

4 Q. As far as like starting with what
5 you consider the most reliable; is that a
6 clinical trial?

7 MR. ORENT: Objection.

8 A. And again, there are different
9 types of research that are graded as far as
10 levels of evidence. The literature talks about
11 Level I evidence being a randomized prospective
12 controlled trial.

13 Q. Mm-hmm.

14 A. Typically the randomization is
15 typically key. So Level II data would be a
16 prospective trial with a cohort or case control,
17 but it's not randomized.

18 Q. Mm-hmm.

19 A. Level III data would be more
20 retrospective with again a case control. And
21 Level IV data would be more of a case series
22 which is more of an observational study.

23 Q. Okay.

24 A. A meta-analysis can be categorized
25 as Level I or Level II depending on the types of

1 studies that they increase -- that they include.

2 Q. Okay. So when you say Level I,
3 you're talking about -- if you go Level I to IV,
4 Level I being like the top?

5 A. Yes.

6 Q. Or the gold standard?

7 MR. ORENT: Objection to the use of
8 the term gold standard.

9 A. It's a ranking --

10 Q. Right.

11 A. -- in terms of how strong would a
12 study be in its design. It doesn't necessarily
13 imply that its conclusions are valid because the
14 study design may be appropriate but the power of
15 the study or the length of follow-up may restrict
16 the applicability of its conclusions.

17 So if you have a study which is a
18 Level I study which has 50 patients in each arm
19 and they followed them for one year --

20 Q. Right.

21 A. -- Level I is good, but the 50
22 patients in each arm may not have been a
23 sufficient number of patients to draw the
24 conclusions, as well as the fact that your
25 conclusions are only good for that one year

1 because beyond that we don't know what happens.

2 Q. Would you agree with me, Doctor,
3 that a Level I study is better than just an
4 observational study?

5 MR. ORENT: Objection, incomplete
6 hypothetical.

7 A. Well, again, it's a little bit of
8 an apples and oranges because a Level I study
9 design is better than a Level IV observational
10 study design, but if you have 50 patients in each
11 arm for a Level I and you have 1500 patients in
12 the Level IV, each of those studies has their
13 pros and cons.

14 Q. Are you a member of the
15 International Urogynecological Association?

16 A. Yes.

17 Q. And also the American
18 Urogynecological Association?

19 A. Yes.

20 Q. And you have been a member since
21 around 1996?

22 A. Yes.

23 Q. And do you consider those
24 organizations important organizations in your
25 field?

1 A. Yes, I think they're organizations
2 which allow an exchange of ideas. They promote
3 the field of urogynecology and encourage research
4 and, again, an exchange of ideas.

5 Q. Have you served on any particular
6 committee or board on either of those
7 organizations?

8 A. So I was part of the coding and
9 nomenclature board of AUGS, and then I'm
10 currently on the mesh special interest group of
11 AUGS.

12 Q. What is the mesh special interest
13 group?

14 A. So sometimes organizations will
15 take certain topics or procedures and say we need
16 more focus on these topics or procedures, and
17 then they'll create a special interest group
18 which is a panel of doctors who have interest or
19 expertise in exploring this on behalf of the
20 organization, creating studies serving as an
21 interaction between industry and the
22 organization, potentially doing scientific
23 analyses, position statements and other
24 scientific endeavors.

25 Q. In conjunction with your role on

1 this special interest group, have you prepared or
2 participated in the preparation of any special --
3 any papers or --

4 A. Not a --

5 Q. -- position statements or --

6 A. So I know we were involved in the
7 position statement that AUGS brought out in terms
8 of --

9 Q. Mesh?

10 A. -- mesh and slings recently.

11 At most of our meetings, it's an
12 open forum so that we have an agenda of what
13 we're going to discuss, and people can present
14 and come and ask questions and see how we're
15 addressing things. And if the organization has
16 specific questions or challenges or projects in
17 our specific field of interest, then they would
18 talk to us about that.

19 Q. So as a member of the mesh special
20 interest group, did you participate in the
21 drafting of any of those position statements?

22 A. Just -- not specifically, in terms
23 of we were able to provide input or basically,
24 you know, say, yes, I want to participate or not
25 I want to participate.

1 Q. What do you mean, yes, you want to
2 participate or no, you don't?

3 A. In the sense that they actually had
4 a core group of people who were doing it, and
5 then they said that if you want to be involved,
6 you can be involved. If you don't want -- the
7 special interest group is oftentimes a very
8 flexible committee which allows you, because
9 everybody has different interests and they're
10 also busy at different times. So they can
11 actually either elect to participate or not
12 participate depending on their level of interest
13 and time available for certain projects. So in
14 the AUGS position statement for slings, I did not
15 actively participate in that.

16 Q. Okay. Now, I may have asked you
17 this before from the beginning, but I just want
18 to just make sure that I have.

19 When were you retained?

20 MR. ORENT: Objection.

21 A. I think it was in November or
22 December of last year.

23 Q. And were you retained by Motley
24 Rice?

25 A. Yes.

1 Q. And have you been retained by
2 Motley Rice in other cases to serve as an expert
3 witness?

4 A. So --

5 MR. ORENT: Objection. And,
6 Doctor, to the extent that you may or may not be
7 working on other projects where you have not
8 disclosed an opinion, that is considered work
9 product, and I would instruct you not to answer
10 to the extent that you may or may not be working
11 on anything that is not before the court or been
12 disclosed.

13 MS. GUILFOYLE: Okay. I think I'm
14 entitled to know whether or not he's been
15 retained by your firm, and if so, on how many
16 cases and information like that. Are you taking
17 the position that's protected? 'Cause I don't
18 believe it is.

19 MR. ORENT: I think he can answer
20 yes or no to that question, but the substance of
21 any opinions, if there are any, would certainly
22 be privileged.

23 MS. GUILFOYLE: I'm not asking him
24 about the substance.

25 MR. ORENT: Okay. Or the

1 identities of any other defendants or things like
2 that. Any details beyond yes or no. Well, let's
3 just take it -- take it with this question first.

4 MS. GUILFOYLE: Right.

5 THE WITNESS: Can you repeat the
6 question?

7 MS. GUILFOYLE: Sure.

8 Have you been retained by Motley
9 Rice in any other cases?

10 A. No.

11 MR. ORENT: That makes it whole lot
12 easier.

13 Q. Do you recognize the name Margaret
14 Thompson?

15 A. Yes.

16 Q. Have you ever been retained by
17 Margaret Thompson?

18 A. On this case, for this report.

19 Q. Okay. Not on any other occasions?
20 Is that your testimony, Doctor?

21 A. Yes.

22 Q. And the point person for purposes
23 of this report, is that Mr. Orent or is that
24 Ms. Thompson?

25 MR. ORENT: That I think gets

1 beyond discoverable material. I'm going to
2 instruct you not to answer on that one.

3 MS. GUILFOYLE: Okay.

4 Doctor, we've marked your report as
5 Exhibit 3, and you -- I believe you've testified
6 that that's a fair and accurate copy of your
7 report, correct?

8 A. Yes.

9 Q. Do you intend to update or
10 supplement this report in any way?

11 A. At the present time, I have no
12 intention of doing that.

13 Q. I noticed in your report, and I can
14 find the section, you said something about if
15 additional information becomes available or you
16 receive additional documents. It's near the end.
17 And I guess I just want to know is that the -- is
18 that the only circumstances under which you
19 intend to potentially supplement your report?

20 A. Yes.

21 Q. And you know what I'm referring
22 to --

23 A. Yes.

24 Q. -- on page 39?

25 A. It's on 38, the second paragraph.

1 Q. What did you do to prepare for this
2 deposition?

3 A. I met with Jonathan yesterday for
4 two hours.

5 Q. Okay.

6 A. And I also re-read my report and
7 did a cursory review of some of the IFUs as well
8 as a few of the papers.

9 Q. Which particular papers did you
10 re-review or do a cursory review of?

11 A. I think -- I don't know exactly
12 which papers. I mean, I literally just scanned
13 them very quickly. It was just in the ones that
14 were in my cited materials folder and literature.
15 I think one of them was the 17 year data on TVT.
16 One was the original paper by Deleval where he
17 talked about the TVT-O modification.

18 Q. Okay.

19 A. The other was the paper by Deleval
20 where he talked about the Abreva modification.
21 And that was mostly what I reviewed.

22 Q. Okay. And you read all of those
23 papers in conjunction with the preparation of
24 your report?

25 A. Previously.

1 Q. Right.

2 A. And most of them previous to even
3 doing the report.

4 Q. Right, right. I was just asking.

5 So going back to the cases in which
6 you offered testimony, are you familiar with the
7 Corriveau versus Bard case?

8 A. Yes.

9 Q. Is there some reason why that case
10 isn't on your list?

11 A. I did a deposition on that case.

12 Q. Okay. Did you have an
13 understanding that this was only trial testimony?
14 'Cause the category says other cases in which I
15 have testified as an expert at trial or by
16 deposition.

17 A. No, my apologies. That was the
18 case I believe I was as a treating physician that
19 I told you about just recently that I did. So I
20 apologize, that was an oversight on my part.

21 Q. 'Cause in fact that was in 2015,
22 right?

23 A. Yes.

24 Q. And in that case, you were
25 testifying as a treater and you were testifying

1 against the Bard product?

2 MR. ORENT: Objection.

3 A. I was just asked to talk about my
4 treatment, about the patient.

5 Q. And you were also retained by Bard
6 previously in the Scott case as an expert on
7 their behalf -- on its behalf, correct?

8 A. Yes.

9 Q. And you testified at trial and at
10 deposition in the Scott matter; isn't that true?

11 A. Yes.

12 Q. Are there any -- now that you
13 understand that you were suppose to include the
14 Corriveau case, are there any other cases that
15 you did not understand you were suppose to
16 include on that expert report?

17 A. Oh, it wasn't so much that I didn't
18 understand. It was an oversight on my part.

19 Q. Okay. Well, any other cases that
20 you believe you have not included on that list?

21 A. Again, not to my recollection.

22 Q. And it's fair to say, Doctor, that
23 the case was not omitted because of the different
24 opinions you took in those two cases, is it?

25 MR. ORENT: Objection.

1 A. I don't understand the question.

2 Q. Sure. Is it fair to say -- it's
3 fair to say, Doctor, that you did not omit the
4 Corriveau case because your opinions in that case
5 were contradictory to those in the Scott case?

6 A. No.

7 Q. So that is fair to say that?

8 A. It's fair to say that, correct. It
9 was an oversight.

10 Q. Can we mark this as Exhibit 4,
11 please.

12 (Whereupon, Deposition Exhibit 4,
13 Dr. N. Kohli Expert Report: Internal
14 Ethicon Documents Cited,
15 was marked for identification.)

16 Q. (BY MS. GUILFOYLE) Doctor, I'm
17 going to show you what's been marked as
18 Exhibit 4, and I will represent to you that that
19 is a list of the Ethicon Bate stamp numbers that
20 appear in your report, but do I understand your
21 testimony to be that you have read more pages
22 than what are necessarily reflected in your
23 report?

24 A. Yes.

25 Q. Now, are there certain pages of

1 Ethicon documents or certain categories of
2 Ethicon documents that you recall reviewing and
3 deciding that they were not pertinent to your
4 opinions or rejecting?

5 A. No, I think most of the
6 documentation was probably pertinent to my
7 opinions. It's just that in my report I
8 essentially quoted or referenced certain
9 documents. And if I quoted or referenced those
10 documents, I put those in my report.

11 Q. When you referenced the depositions
12 earlier, the four depositions, I believe, that
13 you have on your thumb drive, did you read them
14 in their entirety?

15 A. Yes.

16 Q. And did you read all the exhibits?

17 A. To the best --

18 Q. That may have been marked at their
19 depositions?

20 A. I'm not sure if all the depositions
21 had the exhibits attached. I did concentrate on
22 the text of the depositions.

23 Q. Okay. And did you -- in
24 conjunction with reading those depositions, did
25 you feel that you needed additional testimony to

1 put it into context?

2 MR. ORENT: Objection.

3 A. No. I mean, I just read them as
4 they were presented to me in conjunction with all
5 the other documents that I received.

6 Q. Okay. How much time do you
7 currently spend doing legal consulting?

8 A. It probably occupies 10 percent of
9 my practice and time.

10 Q. And for how long a period of time
11 has it occupied approximately 10 percent of your
12 time?

13 A. Probably more recently only because
14 of the amount of information that was required
15 for this type of case. Typically I'm doing one
16 to two -- I'd say two cases per year, medical
17 malpractice mostly. And, again, I would say the
18 vast majority of that is defense with occasional
19 plaintiff work.

20 Q. Have you ever done a medical
21 malpractice case as a defense expert witness in
22 which you defended a doctor's use of the TVT-O?

23 A. Not to my recollection.

24 Q. And then do you also spend a
25 certain amount of your time doing national and

1 international lectures?

2 A. I do. I've done much, much less on
3 the international front in the last three years
4 only because of my young kids, but I will be
5 going to Australia in June -- India in June and
6 Australia in July to give lectures.

7 Q. So in the past four years, say, how
8 much time -- what percentage of your time is
9 spent giving national and international lectures?

10 A. Out of my lecture time or in my
11 entire practice?

12 Q. In your entire practice.

13 A. Oh, again, I would say probably
14 less than 5 to 10 percent. My real concentration
15 is my practice and my patients.

16 Q. Okay. What percentage of your time
17 is spent doing non- -- is educating fellows or
18 teaching at Harvard or any of the other
19 facilities that you're affiliated with?

20 A. So I operate every Monday with the
21 residents at Partners, and then any other time
22 I'm operating at the Brigham a resident or fellow
23 would be involved. So it's hard to differentiate
24 only because that's also counted as clinical time
25 and teaching time. But as far as dedicated

1 lecture time in a classroom with the residents
2 and fellows, it's less than 1 percent.

3 Q. Okay. Have you previously been
4 qualified as an expert witness?

5 A. In what capacity?

6 Q. In any court.

7 MR. ORENT: Objection.

8 A. The Bard case that we talked about.

9 Q. The Scott case?

10 A. The Scott case.

11 Q. Yeah.

12 A. And I think that's it.

13 Q. Has any jurisdiction refused to
14 permit you to offer expert testimony as far as
15 you know?

16 A. So at one point I was asked to
17 provide expert witness on the defense side in
18 Bard, and they evaluated me as an expert, but I
19 was disqualified as I had previously testified on
20 the plaintiff side, or defense side.

21 MR. ORENT: Opposite.

22 THE WITNESS: Opposite.

23 Q. Wait a minute.

24 A. I was asked to potentially be a
25 plaintiff expert for Bard.

1 Q. For Bard?

2 A. Against Bard.

3 Q. Right.

4 A. Well after the Scott case. And
5 then when that was brought in front of the court,
6 they disqualified me because I had done some
7 previous work as a defense expert for Bard.

8 Q. Okay. Actually, can we take a
9 quick break?

10 MR. ORENT: Absolutely.

11 (A break was taken.)

12 Q. (BY MS. GUILFOYLE) So, Doctor, I
13 want to talk about the opinions that you have set
14 forth in your report and which I think you've
15 summarized in the report as well, and starting
16 with the one about polypropylene. Summary of
17 Opinions starts on page 8.

18 A. Yes.

19 Q. And so your first opinion deals
20 with the use of polypropylene in the TVT-O; is
21 that correct?

22 A. Yes.

23 Q. And what is your opinion, Doctor?

24 A. Well, as stated, the inherent
25 properties of polypropylene make it an unsuitable

1 material for placement in the transobturator
2 space. These properties include chronic
3 inflammation, foreign body reaction, shrinkage,
4 contraction, fibrosis and nerve entrapment.

5 Q. So, first of all, any time you
6 implant any type of foreign body into someone's
7 body, it causes a foreign body reaction; isn't
8 that true?

9 MR. ORENT: Objection.

10 A. It can.

11 Q. And polypropylene is considered a
12 suitable material by many organizations; isn't
13 that true?

14 MR. ORENT: Objection.

15 A. Again, I don't know the definition
16 of suitable. Has polypropylene been used by many
17 different surgical specialties and different
18 organizations for surgical procedures in the
19 past, yes.

20 Q. For example, like Prolene sutures.
21 They are as inert as polypropylene, aren't they?

22 MR. ORENT: Objection.

23 A. Again, polypropylene I don't
24 believe is inert, but if Prolene sutures are made
25 of polypropylene, depending on variations in the

1 processing and additives and configuration, it
2 would have a similar reaction.

3 (Whereupon, Deposition Exhibit 5,
4 AUGS Position Statement on Mesh Midurethral
5 Slings for Stress Urinary
6 Incontinence, was marked for
7 identification.)

8 Q. (BY GUILFOYLE) Doctor, I'm going to
9 show you what's been marked as Exhibit 6,
10 Frequently Asked -- Exhibit 5, the "Position
11 Statement on Mesh Midurethral Slings for Stress
12 Urinary Incontinence" by AUGS, and ask you if you
13 have seen that before?

14 A. Yes.

15 Q. And this is an organization that
16 you are a member of, right?

17 A. Yes.

18 Q. And are you familiar with the
19 position statement that AUGS has made on the use
20 of midurethral slings?

21 A. Yes.

22 MR. ORENT: Objection to form.

23 Q. You've read this before, Doctor?

24 A. Yes.

25 Q. Okay. And do you agree with the

1 position of AUGS?

2 A. I can't say that I necessarily
3 agree with all statements.

4 Again, this is a position paper
5 that's written by several authors, and I wouldn't
6 say that I agree with every single statement
7 that's in here.

8 Q. Doctor, and I know that you're
9 trying to be helpful, but there is like a time
10 limit to the depo, too, so if you could try to
11 just focus on the question that I ask you.

12 A. Sure.

13 Q. Are there specific provisions in
14 this -- of this statement that you do not agree
15 with?

16 A. Yes.

17 Q. And what are they?

18 A. Well, the first statement,
19 "Polypropylene is safe and effective as a
20 surgical implant." I don't agree with that
21 statement.

22 Q. Okay. Do you agree that it is safe
23 and appropriate as a surgical implant in any
24 situation?

25 A. Yes, it can be used as a safe and

1 effective implant.

2 Q. Okay.

3 A. But I don't agree necessarily as a
4 blanket statement that it's a safe and effective
5 implant in all situations.

6 Q. Okay. And what about with respect
7 to the use of polypropylene for TVT-O?

8 A. Again, that was one of my opinions,
9 that I didn't believe that polypropylene in the
10 case of TVT-O was a safe and effective implant.

11 Q. And why is that?

12 A. One because of the inherent
13 properties that polypropylene as a foreign body
14 causes, some of those fibrosis and inflammation.
15 Specifically in the space that it's in as well as
16 the structures that it's in causes the
17 complications that are associated with that.

18 Q. Doctor, isn't it fair to say that
19 polypropylene mesh is used in all midurethral
20 slings?

21 MR. ORENT: Objection.

22 A. No. It is used in the vast
23 majority, but there are biologic slings, there
24 are other slings made of different materials,
25 Marlex, Mersilene, but polypropylene is a

1 commonly used material in slings.

2 Q. Okay. Are you aware of any
3 manufacturer that makes midurethral slings that
4 does not use polypropylene?

5 A. Aside from the biologics?

6 Q. Yeah.

7 MR. ORENT: Objection.

8 A. Currently, no.

9 Q. Okay. And, in fact, you implant
10 polypropylene midurethral slings in your
11 practice, don't you?

12 A. Yes.

13 Q. And are you aware of there being
14 any differences in the polypropylene mesh that's
15 used from one midurethral sling to another?

16 A. Yes.

17 Q. And how are you aware of that,
18 Doctor?

19 A. Again, based on my reading of the
20 literature, there are differences in pore size,
21 there are differences in weave configurations,
22 there are differences in weight, there are
23 differences in the length of the sling, there are
24 differences in the processing of the mesh. So
25 those are the differences that I'm aware of.

1 Q. Are you aware of any differences --
2 are you aware of what's considered number one
3 mesh or level one mesh? Does that term mean
4 anything to you?

5 A. Type one?

6 Q. Type one, right.

7 A. So oftentimes the mesh is
8 characterized on whether it's macroporous or
9 microporous --

10 Q. Right.

11 A. -- and that's typically what we're
12 referring to as type one microporous mesh.

13 Q. Mm-hmm. So go to page 2, if you
14 could, Doctor.

15 A. Yes.

16 Q. You don't agree with the statement
17 that polypropylene material is safe and effective
18 as a surgical implant, correct?

19 A. Again, that's a wide ranging,
20 blanket statement which I do not agree with.

21 Q. Okay. And you don't specifically
22 agree that it's appropriate for the use of TVT-O,
23 correct?

24 A. Correct.

25 Q. And it's because of what specific

1 reasons?

2 MR. ORENT: Objection.

3 A. Again, we discussed the in vivo
4 host tissue responses, which include fibrosis,
5 contraction, scarring, and when those responses
6 occur in certain anatomic spaces and through
7 certain anatomic structures, it changes the
8 safety of using that material.

9 Q. Is it the way that the TVT-O mesh
10 is implanted that makes the difference in your
11 mind as far as your opinion?

12 A. Again, if the way it's implanted is
13 speaking to the structures in which it goes
14 through and is involved, then yes.

15 Q. Do you know what the mesh -- the
16 composition of the mesh is that's used in the
17 TVT-O?

18 A. In terms of polypropylene?

19 Q. Yeah.

20 A. It's made of polypropylene, yes.

21 Q. Right. Do you know anything else
22 about it?

23 A. I know it's got a weight of
24 approximately 110 grams per meter squared. It's
25 macroporous. I've seen pictures of the weave.

1 I've had the opportunity to use that mesh on
2 multiple occasions.

3 Q. Is it your testimony, Doctor, that
4 this polypropylene mesh that is used in
5 suburethral slings is safe and effective to be
6 used in every other manufacturer's suburethral
7 sling other than the TVT-O?

8 MR. ORENT: Objection to the term
9 suburethral sling.

10 Q. Midurethral sling. Sorry.

11 A. I feel it's safe in the use of the
12 retropubic suburethral sling, but in terms of the
13 obturator sling where it goes through those
14 structures, I don't feel that that material is
15 safe.

16 Q. Is it your testimony, Doctor, that
17 the use of polypropylene mesh is not safe in any
18 obturator midurethral sling?

19 A. I think there are relative grades
20 of safety, and comparatively speaking,
21 transobturator outside-in versus transobturator
22 inside-out, the safety profile for the inside-out
23 is significantly less in terms of risk to the
24 patient, higher risk to the patient.

25 Q. And what kind of training do you

1 have to make that opinion, Doctor?

2 A. As an implanter of over 3,000 mesh
3 products, 50 to 100 TVT-Os to 2,500 to 3,000
4 retropubic slings, it would be my clinical
5 experience as a surgeon as well as not only an
6 implanter but an explanter.

7 Q. Do you have any studies that you
8 rely on to support that position?

9 A. Well, I know that there have been
10 some anatomic studies about the surgical variants
11 of the TVT-O mesh in terms of its relationship to
12 critical structures. I also know that there have
13 been studies from Deleval himself where he talks
14 about the polypropylene mesh and how it can cause
15 fibrosis through the muscles where the TVT-O was
16 placed, and therefore the development of the TVT
17 Abreva was in order to address those issues.

18 Q. Doctor, I'm really only directing
19 my questions about the TVT-O.

20 A. Correct, and I answered your
21 question in terms of the anatomic studies of
22 TVT-O as well as the TVT-O paper that Deleval
23 himself has written which talks about the TVT-O.

24 Q. And what are the anatomic studies
25 you're referring to?

1 A. I believe it was -- I would have to
2 look at those and get you those particular
3 references, which I don't have off the top of my
4 head. Which I can provide those to you.

5 Q. You don't recall them as you sit
6 here now?

7 A. I don't.

8 Q. Okay. Well, you can look -- maybe
9 during a break you can look at them.

10 A. Sure.

11 Q. So number 2, "The monofilament
12 polypropylene mesh MUS is the most extensively
13 studied anti-incontinence product in history --
14 procedure in history." Do you agree with that,
15 Doctor?

16 A. I think if you look at the -- yes.

17 Q. Number 3, "Polypropylene mesh
18 midurethral slings are the standard of care for
19 the surgical treatment of SUI and represent a
20 great advance in the treatment of this condition
21 for our patients." Do you agree with that
22 statement of AUGS?

23 MR. ORENT: Objection.

24 A. No.

25 Q. And why is that?

1 A. There are a great number of my
2 colleagues around the country who feel that
3 synthetic suburethral slings present significant
4 risk, and many of them are continuing to do
5 traditional therapy such as Burchs or cadaveric
6 fascial slings. And if you believe in this
7 statement that this is the standard of care, all
8 of them would be falling below the standard of
9 care. And I don't think that -- there are a
10 variety of incontinence procedures, and I just
11 don't feel like the polypropylene sling is the
12 only standard of care. We have various treatment
13 options for this condition. There are some, many
14 in this country, who choose not to use a
15 synthetic mesh.

16 Q. And you know that from what,
17 discussing that with them?

18 A. I know that from teaching
19 nationally, talking to colleagues, looking at
20 surveys that organizations have done about how
21 many of you are using slings and not using slings
22 and talking to my colleagues.

23 Q. So do you know whether or not AUGS
24 did a survey before they came out with what's
25 referred to as number 3 in their position

1 statement?

2 A. Yes.

3 Q. And do you know whether that survey
4 is accurate?

5 MR. ORENT: Objection, foundation.

6 A. Again, if you look at study design,
7 there's biases in who answers surveys and who
8 doesn't answer surveys. And although the study
9 may reflect that number, whether it's accurately
10 reflecting the body of surgeons in this country
11 it doesn't. And the other is that this was only
12 for AUGS members. A large number of slings are
13 being presented by or performed by urologists or
14 gynecologists who aren't AUGS members, and so the
15 numerator and denominator in this type of
16 analysis is incomplete.

17 Q. Doctor, as far as AUGS members, do
18 you have any reason to believe that what's
19 reflected in statement 3 did not represent the
20 position of the AUGS members who may have
21 participated in any survey?

22 MR. ORENT: Objection, foundation.

23 A. Again, if their survey said greater
24 than 99 percent of AUGS members looking at
25 details of study design of the survey, I'll take

1 the 99 number, but there are reservations and
2 discussions that you can have about study design.

3 Q. Doctor, do you know whether or not
4 a study was done, and if so, there was -- I mean
5 a questionnaire was done, and if so, the exact
6 results of the questionnaire?

7 A. Yes, so that's a different
8 question. So they did give the survey, and this
9 reflects the results of the study.

10 Q. Okay. Accurately, fair to say?

11 MR. ORENT: Objection.

12 A. As far as what the study reported,
13 yes.

14 Q. Number 4, "The FDA has clearly
15 stated that the polypropylene MUS is safe and
16 effective in the treatment of SUI." Do you agree
17 with that, Doctor?

18 MR. ORENT: Objection.

19 A. Again, I mean, the quote of the FDA
20 is here, and I agree that the FDA said that.

21 Q. Okay. It's just you don't agree
22 with that. Is that it?

23 A. Again, they've put minimally in
24 use -- minimally invasive slings, midurethral
25 slings. They've included lots of slings, but

1 then they qualify it to say single-incision
2 slings are not included. They didn't do a
3 breakdown of transobturator versus retropubic.
4 But in terms of your question do I agree that the
5 FDA has stated what they've stated on this piece
6 of paper, yes.

7 Q. And your opinion with respect to
8 the use of polypropylene mesh in midurethral
9 slings pertains only to the outside-in slings
10 like the TVT-O?

11 MR. ORENT: Objection.

12 A. And which opinion specifically are
13 you asking about?

14 Q. Well, you talk about, well, in some
15 cases the use of polypropylene mesh is acceptable
16 for a midurethral sling but certainly in the
17 TVT-O it's not.

18 A. Correct.

19 Q. Is there any specific product other
20 than the TVT-O that you feel using polypropylene
21 mesh is inappropriate?

22 A. Over the last several years, we've
23 come -- again, myself and clinically in my own
24 practice, I've come to the feeling that the
25 transobturator sling is associated with a

1 different set of complications.

2 The TVT-O specifically, again, my
3 issue is the structures that it passes through
4 and the ability to actually explant that in cases
5 of complication.

6 Q. Okay. Well, the explant that we're
7 going to deal with is a separate opinion of
8 yours.

9 A. Sure.

10 Q. But am I correct that you don't
11 specifically recall with the 50 to 100 TVT-O
12 slings that you implanted what sort of
13 postoperative complications your patients had?

14 A. Correct.

15 Q. Okay. So when you say based on my
16 clinical experience, your clinical experience is
17 something that you don't even recall?

18 MR. ORENT: Objection.

19 A. No, because I've had other clinical
20 experience in taking care of other patients who
21 have had TVT-O outside of the numbers that we
22 talked about in my own cases.

23 Q. Okay. So let me clarify that,
24 then. But it's fair to say that with respect to
25 the TVT-O sling, you have no recollection of

1 whether your patients, the 50 to 100 that you
2 implanted the TVT-O sling, had any complications
3 post surgical?

4 MR. ORENT: Objection.

5 A. Correct, not to my recollection.

6 Q. Okay. And so when you talk about
7 your clinical experience, you're not even talking
8 about them. You're talking about any type of
9 explant that you may have done.

10 A. And other patients that I've seen
11 with complications from the product.

12 Q. Okay. So how many patients have
13 you treated for alleged complications with the
14 TVT-O sling?

15 A. Again, I would probably say it's in
16 the 30 to 50 range.

17 Q. And what were the complications?

18 A. Mostly they were centered around
19 pain.

20 Q. Okay. And these are patients that
21 you didn't treat before they came to see you,
22 right? I mean -- strike that.

23 These are patients that you did not
24 treat prior to the implant of the sling?

25 A. Correct, I was not their surgeon or

1 taking care of them. They had the surgery
2 elsewhere, and then they saw me.

3 Q. And to some extent when you're
4 seeing strictly as an explanter, you're not
5 getting the full picture of what the implanter
6 may or may not have encountered during the
7 surgery; isn't that fair to say?

8 MR. ORENT: Objection.

9 A. Correct, I typically try to get
10 access to the operative notes and the
11 preoperative records, but that would be my
12 exposure to the preoperative and intraoperative
13 course of that patient.

14 Q. You're not talking to the
15 implanting doctor and finding out specifics or
16 particular issues relative to a single plaintiff,
17 are you?

18 A. Typically, no, unless that doctor
19 calls and says I want you to see my patient and
20 just to let you know this is what happened if
21 something out of the ordinary happened but
22 typically no.

23 Q. And you would agree with me
24 wouldn't you, Doctor, that there can be a number
25 of non-mesh related reasons for somebody

1 encountering complications during a surgical
2 procedure?

3 MR. ORENT: Objection, form.

4 A. Yes.

5 Q. And in fact many of the patients
6 that are implanted with midurethral slings in
7 fact have other health conditions that complicate
8 their surgical recovery; isn't that true?

9 MR. ORENT: Objection.

10 A. So what conditions are you
11 specifically talking about?

12 Q. Obesity, for example. Smokers,
13 age, other health conditions that impact your
14 ability to heal.

15 A. Again, I think smoking has been
16 shown to potentially be a factor in healing. We
17 haven't found in our own surgical experience that
18 a lot of those factors are making a big
19 difference in their postoperative complications
20 or healing or recovery.

21 Q. What about obesity, Doctor?

22 A. Again --

23 MR. ORENT: Objection.

24 A. -- unless they are diabetic related
25 to the obesity and they have poor blood sugar or

1 on steroids, and that is more germane in the
2 healing process. Obesity as an independent risk
3 factor for poor healing, we haven't necessarily
4 found that in our practice or in my practice.

5 Q. What about infection rates at a
6 particular hospital? What impact, if any, can
7 that have on the success rate of an implant?

8 A. It can obviously have an impact if
9 you have an infection. Again, our infection
10 rates are extremely low, and I would probably say
11 they're under 1 to 2 percent. Maybe because of
12 our surgical technique, maybe because of the
13 routine use of antibiotics and maybe because of
14 the type of hospitals we operate at which tend to
15 be more community as opposed to tertiary care
16 where infections may be more prevalent in the
17 operating room.

18 Q. But is that where you're getting
19 all your referrals for the explants or treatments
20 post implant?

21 MR. ORENT: Objection.

22 A. When you say "where," specifically
23 what do you mean?

24 Q. They're not just from the hospitals
25 that you work at or are they?

1 A. Oh, no, they're from all over the
2 New England area.

3 Q. Right. So in many cases, they're
4 from hospitals that you have no familiarity with
5 and have no understanding of what their infection
6 rate may be; isn't that true?

7 A. Correct.

8 Q. And often a person can have
9 other -- well, let me ask you that. Are there
10 other health conditions that can complicate the
11 success rate of the use of a midurethral sling?

12 A. Are you talking success rate or
13 complication rate?

14 Q. Complication rate.

15 A. Again, we talked about some of
16 them. If you have nutritional deficiency or
17 smoking, that could cause poor wound healing. If
18 you have diabetes or steroid use, that could
19 cause it. If you are on a blood thinning
20 medication, that potentially could cause a higher
21 risk of infection and hematoma. If you had
22 multiple other surgeries, that could make the
23 surgical space scarred and complicated. Those
24 are probably the major things we look at in terms
25 of taking a patient to the operating room in

1 terms of her intra- and post-operative
2 complication rates.

3 Q. Okay. And of the 30 to 50 patients
4 that you have treated for after implant
5 complications or concerns, what percentage have
6 you opted to remove the sling.

7 MR. ORENT: Objection.

8 Q. If you can recall.

9 A. So the vast majority we will remove
10 the sling because typically they have significant
11 pain on palpation of the sling, and that's kind
12 of what our marker is. If they have significant
13 pain on palpation of the sling, it's logical that
14 it should be removed.

15 When we talk about removal, that's
16 a difficult question because we approach it in
17 one of two ways. If most of the pain is in the
18 vaginal area, we typically will recommend a
19 segmental excision where we remove that portion
20 of the mesh that's causing pain.

21 Some of these patients are having
22 either unilateral or bilateral groin pain. And
23 for those patients, we typically will recommend
24 complete removal of that portion of the mesh that
25 goes through the obturator space.

1 So when we talk about removal, it's
2 usually either complete which talks about that
3 portion in the obturator space or segmental which
4 is mostly limited to the suburethral or vaginal
5 portion of the mesh.

6 Q. So of the 30 to 50 people that
7 you've treated, have you removed the mesh or
8 recommended removal of the mesh in all of those
9 patients?

10 A. Some of the patients -- we've
11 recommended it on most of the patients. Some of
12 the patients have opted not to do anything
13 because of the risks associated with removal.
14 Some of them have opted for either physical
15 therapy or trigger point injections because,
16 again, their approach to surgery and potentially
17 their severity of their symptoms, and some of
18 them have opted for removal.

19 Q. You would agree with me, would you
20 not, Doctor, that there are a number of causes of
21 pelvic pain that are unrelated to the implant of
22 a sling?

23 MR. ORENT: Objection.

24 A. Yes.

25 Q. And, in fact, in many of -- in many

1 people who have slings implanted, they had pelvic
2 pain before and continue to have pelvic pain
3 after?

4 MR. ORENT: Objection, foundation.

5 A. Again, in our practice, we're very
6 hesitant to put slings and do significant pelvic
7 surgery in patients with pelvic pain. I can't
8 recall those patients from the outside who were
9 sent to us for mesh complication how many of
10 those patients had chronic pain, but typically
11 when we are operating on a patient for pain, it's
12 because there's significant tenderness in the
13 area of the mesh itself.

14 Q. Right, but you can't rule out that
15 the tenderness that you find when you're
16 examining the patient is due to other conditions
17 unrelated to the mesh, can you?

18 MR. ORENT: Objection.

19 A. Well, when we're touching just the
20 area of the mesh, there's nothing else there but
21 the mesh, so we do rule that out.

22 If there are other symptoms or
23 other areas of pain involvement, then there could
24 be coexisting processes going on.

25 Q. And pain is a subjective

1 determination, would you agree?

2 MR. ORENT: Objection.

3 A. Pain is a subjective complaint by
4 the patient, and tenderness is an objective
5 observation by us during an examination.

6 Q. But the tenderness that you see is
7 based on a subjective response.

8 MR. ORENT: Objection.

9 A. In the patient reporting pain.

10 Q. Right.

11 A. Yes.

12 (Whereupon, Deposition Exhibit 6,
13 AUGS Frequently Asked Questions by
14 Providers Mid-urethral Slings for Stress
15 Urinary Incontinence,
16 was marked for identification.)

17 Q. (BY MS. GUILFOYLE) All right, I'm
18 going to show you what's been marked as
19 Exhibit 6, Doctor, and ask you to take a look at
20 this. Have you seen this before?

21 A. Yes.

22 Q. And are there any portions of this
23 "Frequently Asked Questions by Providers
24 Mid-urethral Slings for Stress Urinary
25 Incontinence" that you do not agree with?

1 A. Yes.

2 Q. What portion?

3 A. "Does the evidence indicate that
4 mid-urethral slings are safe in the treatment of
5 SUI?"

6 Q. And that's, again, in -- you don't
7 agree with it because of your position with
8 respect to the TVT-O?

9 A. Well, I don't agree with it because
10 they say that the only specific complications
11 related to mesh use when we compare it to
12 non-mesh procedures is vaginal mesh exposure and
13 mesh perforations into the urinary tract, and I
14 don't agree with it because there are mesh
15 perforations into the bowel, which, again, if you
16 didn't use a mesh you wouldn't have a mesh
17 perforation, as well as the fact that I think
18 dyspareunia and pain can oftentimes be related to
19 the mesh which they don't -- that they
20 essentially exclude.

21 So I would say that the reason I
22 don't agree with that is because I feel like the
23 complications that are specifically listed in
24 terms of vaginal mesh are incomplete.

25 Q. Have you read any studies, Doctor,

1 that show a connection between the use of the
2 TVT-O midurethral sling and dyspareunia and pain?

3 A. I've read studies that show that
4 transobturator slings in general have a banding
5 effect in the vagina. Which of those slings that
6 they studied, I don't recall in terms of which --
7 if they were TVT-O or outside-in transobturator
8 slings.

9 We have found or I have found in my
10 clinical experience and my clinical practice when
11 you have a transobturator procedure you can have
12 pain in the vagina and the groin area, so we've
13 noticed that on our patients, and some of those
14 patients have had TVT-O, and some of those
15 patients have had transobturator.

16 Q. Okay. So when you're talking about
17 that the patients in your experience, you're
18 talking about the 30 to 50 that have come to you
19 after they've been implanted and after they've
20 suffered complications, right?

21 A. Yes.

22 Q. Is there anything else about this
23 position paper you don't agree with, Doctor?

24 A. Again --

25 MR. ORENT: Objection.

1 A. -- the same concept as opposed to
2 the position paper on meshes where it says that
3 what is the material used and has it been safe,
4 they make a wide sweeping statement that all
5 polypropylene is safe, and I don't necessarily
6 agree with that in terms of how it's been used.

7 Q. So is your testimony with respect
8 to the polypropylene related to its use in
9 certain mesh in certain slings, or is it related
10 to the composition of the mesh?

11 A. So it's mostly related to using
12 polypropylene in certain areas, in anatomic
13 areas, in terms of what risks and complications
14 can occur because of meshes in that area and what
15 would be the potential treatment, i.e., removal
16 of those complications.

17 Q. Okay. And are you familiar with
18 anything other than I guess your 30 to 50
19 patients that you treated that indicates that the
20 use of mesh for the TVT-O in that particular area
21 where it's implanted causes problems with people?

22 A. Oh, I think there's a variety of
23 data that talks about groin pain and dyspareunia
24 in TVT-O, and some of it is actually chronic and
25 long term.

1 Q. But do you recall what they are,
2 Doctor?

3 MR. ORENT: Objection.

4 A. Again, I'd be happy to give you
5 those references. And I also know that there was
6 one paper which was a meta-analysis or review of
7 the MAUDE database which also talks about the
8 complications of that, as well as, again,
9 Dr. Deleval's most recent paper where he talks
10 about the Abreva where he really talks about one
11 of the reasons the Abreva was introduced or
12 developed was to address the concern of groin and
13 thigh pain related to TVT-O.

14 Q. Okay. Is there anything else that
15 you rely on?

16 A. Just general review of the
17 literature and my clinical experience in
18 patients.

19 Q. All right. But your clinical
20 experience in patients is related to that 30 to
21 50 --

22 MR. ORENT: Objection.

23 Q. -- isn't that true?

24 A. In the patients that I've taken
25 care of, yes, yes.

1 Q. Right, right. I mean, you can't be
2 relying on your clinical treatment of other
3 patients if it's not -- if, one, you don't
4 remember them or, two, it's not related to the
5 TVT-O.

6 A. Correct.

7 MR. ORENT: Objection.

8 Q. All right. You agree with that?

9 A. Yes.

10 Q. Now, do you recall being questioned
11 at the -- well, do you recall giving testimony in
12 the Scott case?

13 A. Yes, but I didn't review that
14 deposition for today.

15 Q. That's okay. Do you recall being
16 questioned about the use of polypropylene?

17 A. Yes.

18 Q. Okay. What do you recall about
19 that? You're sort of smiling. I don't know
20 whether something's coming to mind --

21 A. Oh, no. I don't recall the
22 specifics. I do know that that was part of the
23 questioning. I don't recall the specifics, but
24 I'd happy to review any specifics you'd like to
25 talk to me about.

1 (Whereupon, Deposition Exhibit 10,
2 3/1/12 Deposition of Dr. Kohli
3 was marked for identification.)

4 Q. (BY MS. GUILFOYLE) Doctor, you have
5 before you what's marked as Exhibit 10, and I
6 will represent to you that is testimony,
7 deposition testimony, from the Scott versus Bard
8 case. And if I could ask you to turn to page 17
9 and in particular line 27.

10 MR. ORENT: There's no line 27 on
11 17.

12 MS. GUILFOYLE: Can we go off the
13 record for a minute.

14 (A break was taken.)

15 (Whereupon, Deposition Exhibit 11,
16 Trial testimony of Dr. Kohli,
17 was marked for identification.)

18 Q. (BY MS. GUILFOYLE) I'm going to
19 show you, Doctor, what was marked as Exhibit 11.

20 A. Okay.

21 Q. I'll represent to you that's a
22 rough draft of trial testimony by you in the
23 Scott case. Have you seen that before?

24 A. I don't recall if I've seen it.

25 Q. Okay. If I could direct your

1 attention to page 17, and if you could read to
2 yourself the question and then read out loud the
3 answer. Actually I'll -- yeah. Are you ready?

4 A. I'm on page 17.

5 Q. Okay. So on 22 is the question.

6 A. Would you like me to read it?

7 Q. Yeah.

8 A. "The Jury has heard that the pelvic
9 organ prolapse kits particularly Avaulta Plus
10 made of polypropylene are the slings and the TVT
11 procedure you were discussing earlier are they
12 made of polypropylene mesh, too?"

13 Q. And then your answer, Doctor?

14 A. "Polypropylene has slowly filtered
15 out to us to be the safest style of synthetic
16 mesh we can use. We have used a variety of
17 synthetic meshes. Artificial meshes in the
18 pelvis and for general surgery over the last 50
19 to 60 years the first nylon mesh was first
20 described in 1956 so we have had 50 years of
21 experience with synthetic materials over time as
22 we become smarter as tissue engineering has
23 become more coordinated with the medicine we
24 realize that certain materials are safer.
25 Certain weaves are safer. Certain structures are

1 safer and currently the general thinking across
2 our society and our leadership out of all the
3 artificial materials polypropylene is probably
4 the safest."

5 Q. Okay, thank you. So that was
6 accurate testimony when you gave it at trial
7 under oath, correct?

8 A. Yes.

9 Q. Now, one of the opinions that you
10 set forth in your report, Doctor, is that there
11 is a safer alternative to the use of the TVT-O,
12 correct?

13 A. Yes.

14 Q. Okay. And what is it that you rely
15 on for your opinion?

16 A. Well, I rely on my own clinical
17 experience and my history of taking care of
18 patients as well as some of the literature I've
19 reviewed and books I've read and discussions I've
20 had with colleagues and physicians.

21 Q. And the safer alternatives that you
22 recommend are in part non-mesh procedures?

23 A. Well, I think there's a variety of
24 safer alternatives for incontinence, including
25 non-mesh procedures which we talked about, Burch

1 colposuspension, autologous slings, even the
2 needle suspension procedures which might be
3 safer. I also think that the retropubic TVT is
4 probably a safer procedure as well.

5 Q. Isn't it true if we're talking
6 about the Burch procedure and autologous -- did I
7 pronounce that right?

8 A. Autologous.

9 Q. -- autologous slings that those
10 aren't always an option for an individual
11 patient?

12 A. I don't know if you would clarify
13 which patients they're not an option for. It
14 really depends on the surgeon's experience. It
15 depends on their skill set. The current group of
16 surgeons who are currently practicing
17 urogynecology there's a generational gap where
18 they haven't done Burchs. So clearly if they
19 were to recommend a Burch now to a patient, that
20 might be risky in the sense that they don't have
21 experience or expertise doing that procedure.

22 Q. But when you do the Burch
23 procedure, don't you have to harvest tissue from
24 elsewhere in the body?

25 A. No, that is the sling procedure.

1 The Burch procedure is actually a series of
2 sutures which are placed in the pubocervical
3 fascia and the periurethral tissue which anchors
4 that tissue to the Cooper's ligament.

5 Q. But the autologous sling is you
6 harvest tissue --

7 A. So the sling procedure --

8 Q. -- is that correct?

9 A. In the autologous sling, correct,
10 but there are other sling procedures that can use
11 biologic materials where you wouldn't have to
12 harvest.

13 Q. Okay. And these require additional
14 incisions and invasiveness, correct?

15 MR. ORENT: Objection.

16 A. It depends on your technique and
17 what material you're using. Oftentimes you can
18 do it through the small incision that you make
19 for the sling if you're using rectus fascia.
20 Some people use vaginal wall, and you can do it
21 through the same vaginal incision you're doing.
22 So depending on the technique and what material
23 you're using, it may or may not require a
24 separate incision or longer operative time.

25 Q. Isn't it true, Doctor, that the

1 studies indicate that non-mesh repair for stress
2 urinary incontinence have a higher recurrence
3 rate?

4 MR. ORENT: Objection. It's an
5 incomplete.

6 A. Again, if you look at the long-term
7 outcomes, some of the studies have shown very
8 good outcomes with biologic fascial slings and
9 Burch colposuspensions, and some of the studies
10 have shown very good long-term outcomes with
11 synthetic slings.

12 Q. Is it your testimony, Doctor, that
13 the medical literature out there does not support
14 the position that if you use the Burch procedure
15 or autologous slings that you're more likely to
16 have to repeat the procedure?

17 A. That's not necessarily my position.
18 More likely to repeat the procedure is difficult
19 to say because some patients if they have
20 recurrence of their incontinence may not
21 necessarily want another procedure.

22 In addition, I do think that the
23 success rates with midurethral slings are high,
24 but again, there is a variation. As we talk
25 about midurethral slings, we talk of them as a

1 large class, and there are individual procedures
2 and techniques within that class, and some of the
3 success rates are very low. If you want to talk
4 about midurethral slings such as the
5 single-incision slings such as TVT Secur, that
6 success rate is significantly lower long term
7 than the Burch.

8 So when you say comparing a Burch
9 long term to a midurethral sling, because the
10 midurethral sling is such a large class of types,
11 the success rates may not necessarily be as good
12 long term.

13 Q. How about versus the TVT-O?

14 A. To my knowledge, I don't know if we
15 have the same long-term data comparing how long
16 we've studied the long-term effects of a Burch or
17 a non-synthetic midurethral sling compared to a
18 TVT-O. I would have to look that information up.

19 Q. Okay. So you're not aware as you
20 sit here today of any studies that address that?

21 A. Not off the top of my head.

22 Q. Okay. Did you look for any when
23 you were coming up with the opinions in your
24 report?

25 A. I looked at a lot of the

1 comparative studies about TVT versus TVT-O and
2 those types of studies but not necessarily
3 against some of the more traditional treatment
4 options.

5 Q. Have you read any studies that talk
6 about the efficacy rate of the Burch procedure?

7 A. Yes.

8 Q. Okay. And what is the efficacy
9 rate?

10 A. Again, I can't quote the studies
11 right off the top of my head, but I'm estimating
12 in the 10- to 15-year range it's still in the 70
13 to 80 percent range. Some of the midurethral
14 sling studies have shown a much lower success
15 rate over that time period, and some of them
16 shown a much higher success rate.

17 Q. Are you aware of studies that show
18 that the TVT-O has a higher success rate than the
19 Burch procedure?

20 A. Not off the top of my head, but I
21 could, again, relook at those references and then
22 answer that question.

23 Q. Well, would it surprise you if I
24 told that there are?

25 MR. ORENT: Objection.

1 A. If you say that there are and I
2 would look at the literature, I'd be happy to
3 look at it.

4 Q. Well, Doctor, I'm here to ask you
5 questions about what you rely on for your
6 opinions. So if you don't know the answer now,
7 you can feel free to just tell me that.

8 A. Correct, off the top of my head I
9 do not have access to that information.

10 Q. Okay. And what about -- did you
11 ever have -- well, what about the autologous
12 slings? Are you aware of literature out there
13 that indicates that the success rate of the TVT-O
14 is higher than that, than the autologous slings?

15 A. I have not -- to my knowledge, I
16 don't know of any randomized prospective
17 controlled trials looking at the long-term data
18 of one versus another.

19 Q. What about any type of medical
20 literature, Doctor?

21 A. Again, I'm sure that there is
22 comparative series where you could look at how
23 one doctor did a fascial sling or a traditional
24 sling and looked at his patients over ten years
25 and then looked at the TVT-O data of another

1 doctor, but I can't quote that off the top of my
2 head.

3 Q. Okay. So as you sit here today,
4 you can't give it to me?

5 MR. ORENT: Objection.

6 A. Correct.

7 Q. I'd ask you to look at what's
8 Exhibit 11, the trial testimony again.

9 Okay, Doctor, if you could turn to
10 page 80 of this transcript. And in particular,
11 if you could go to lines 15 to 23.

12 MR. ORENT: I'm sorry, what page
13 was that?

14 MS. GUILFOYLE: 80.

15 And in this portion, I'll represent
16 to you you talk about the success rates of the
17 slings versus other procedures, and in particular
18 at line 15 you say, "So our failure rates for
19 traditional repairs are about 30 percent. So one
20 in three women who need another -- will need
21 another surgery or may get another surgery down
22 the road. When we use a mesh our failure rate
23 goes to 10 percent. So one in ten. So what I
24 tell my patients is are you willing to take a 20
25 percent reduction in recurrence for a 5 percent

1 risk of complication. And if you are, then let's
2 go with mesh." Did I read that correctly.

3 MR. ORENT: Objection.

4 A. You did but out of the wrong
5 context.

6 Q. Okay.

7 A. We were talking here about mesh for
8 prolapse, and I don't think we were specifically
9 talking about slings.

10 Q. Okay. Fair enough, Doctor. Mark
11 this as the next exhibit.

12 (Whereupon, Deposition Exhibit 12,
13 AUA Guideline for the Surgical Management
14 of Female Stress Urinary Incontinence:
15 2009 Update, was marked for identification.)

16 Q. (BY MS. GUILFOYLE) Doctor, I'm
17 going to show you what's been marked as
18 Exhibit 12 --

19 A. Thank you.

20 Q. -- and ask you if you recognize
21 that?

22 A. I don't think I have reviewed this
23 paper.

24 Q. Okay. I want to direct your
25 attention to specific -- are you familiar with

1 this organization?

2 A. Yes.

3 Q. Okay. To specific pages. So if

4 you could go to page -- they're not numbered.

5 Table 16.

6 A. Appendix A16?

7 Q. Yeah. Where the title is

8 "Complications Rate - No Prolapse."

9 A. Okay.

10 Q. And do you see the one that says

11 "Burch Suspension"?

12 A. Yes.

13 Q. And it talks -- and then the

14 subject of complications on the left are pain,

15 sexual dysfunction and voiding dysfunction. Do

16 you see that?

17 MR. ORENT: Objection.

18 A. Yes.

19 Q. Okay. And they have pain 6

20 percent, sexual dysfunction 3 percent, voiding

21 dysfunction 10 percent. Did I read that

22 correctly?

23 MR. ORENT: Objection.

24 A. Yes.

25 Q. And then if you go to the next page

1 where it talks about the autologous fascia at the
2 top, and it has the same subjective complications
3 on the left. Do you see that?

4 A. Yes.

5 Q. And it has pain 10 percent and
6 sexual dysfunction 3 percent.

7 A. 8 percent, I believe.

8 Q. 8 percent, right. Thank you. Did
9 I read that correctly?

10 MR. ORENT: Objection.

11 A. Yes.

12 Q. Do you have any reason to doubt the
13 accuracy of those statistics?

14 A. Again, I haven't had a chance to
15 review this paper or the methodology, but I have
16 no reason to doubt it.

17 Q. Okay. Now, one of the opinions
18 that you give, Doctor, was that the TVT-O was
19 approved based on TVT as a predicate device,
20 although they had -- they share little clinical
21 resemblance. Do you recall that opinion?

22 A. Yes.

23 Q. Now, you're not a regulatory
24 expert, are you?

25 A. I don't know how you would define

1 expert.

2 Q. Have you worked for the FDA?

3 A. I have not worked for the FDA.

4 Q. Have you studied the regulatory
5 rules for submission of any kind of documents by
6 a medical device manufacturer to the FDA?

7 A. I serve as chief medical officer
8 for a company called ME Medical, and over the
9 last two years we have developed, designed and
10 manufactured a urinary catheter in the area of
11 urogynecology, and as part of that process, we
12 were involved in submitting to the FDA, and I was
13 involved in that.

14 Q. Okay. Were you submitting it as a
15 predicate device, Doctor?

16 A. It's submitted as a predicate
17 device based on a urinary catheter.

18 Q. Okay. And you did that on your own
19 without any legal counsel? Is that your
20 position?

21 A. Oh, no. I just said that we did it
22 as part of my involvement as chief medical
23 officer. We had significant input from the rest
24 of the management team as well as legal counsel
25 as needed.

1 Q. Okay. And you'd agree with me that
2 the mesh used in the TVT and the TVT-O is the
3 same, correct?

4 MR. ORENT: Objection.

5 A. Yes.

6 Q. And you'd also agree with me that
7 the only thing that remains in the body following
8 insertion is the mesh, correct?

9 A. Yes.

10 Q. In both products?

11 A. Yes.

12 Q. What factual evidence do you have
13 to state -- to support your opinion that this was
14 not a proper predicate device?

15 A. Well, my statement was that they
16 share little clinical resemblance.

17 Q. Okay. So you're not challenging --

18 A. So I can't comment on that.

19 Q. -- whether or not it was an
20 appropriate predicate device?

21 MR. ORENT: Objection, misstates
22 his testimony.

23 Q. Is that what you're saying?

24 A. I'm not challenging the ruling of
25 the FDA. I'm challenging that their argument

1 that this was very similar between the two is
2 like saying that a car and a bicycle with
3 training wheels both have four wheels and they
4 both are used to go from Point A to Point B, but
5 that doesn't mean that both of them are similar
6 or that I would put an 8-year-old in a car. And
7 so my feeling was is that they did not have
8 significant clinical resemblance, exactly how I
9 state it.

10 Q. Okay. What evidence do you have,
11 Doctor, to support your position that the TVT-O
12 is a defective design?

13 A. Again, we discussed this
14 previously, and I do talk about specifics of this
15 which are based on my clinical experience, my
16 teaching for Gynecare, my review of the
17 literature as well as the review of internal
18 Gynecare documents. It's blind insertion of a
19 permanent device through the transobturator space
20 which is a space that many surgeons and
21 gynecologists and urogynecologists previously did
22 not have a lot of familiarity with. My issue
23 really is placement of a polypropylene mesh which
24 is a permanent material which can cause fibrosis,
25 contraction, scarring through a space which has

1 significant anatomic structures makes it
2 difficult to remove in its entirety, and we
3 talked a little bit about the fact that the
4 inside-out approach anatomically put certain
5 structures at higher risk, and we also talked
6 about the fact that the distance between
7 inserting the needle and retrieving the needle in
8 the TVT-O is about 4 to 5 centimeters as opposed
9 to the transobturator sling which is typically
10 between 1 and 2 centimeters, and typically the
11 proportion or the risk of a patient is
12 proportionate to the distance of blind needle
13 passage and the position of critical structures
14 in that space.

15 Q. And what do you base that position
16 on, Doctor?

17 A. My clinical experience as a surgeon
18 performing these as well as anatomic studies that
19 I've looked at.

20 Q. Except the clinical experience as a
21 surgeon performing these you don't remember
22 anything about that.

23 MR. ORENT: Objection.

24 A. No, I think you're misstating me.
25 I told you that I don't specifically remember any

1 complications that we had, but as far as my
2 clinical experience performing the procedure, I
3 have full knowledge and recollection of
4 performing the procedure as well as doing
5 multiple training programs at cadaver labs and
6 teaching of physicians on the technique.

7 Q. Okay. And you were able to do it
8 successfully, correct?

9 A. Yes.

10 Q. Are you aware of studies that
11 indicate that the TVT-O is as good as if not
12 superior design to the TVT?

13 A. Can you define what you say in
14 terms of superior?

15 Q. Well, it's effective, lack of
16 complications, lack of recurrence.

17 A. So, again, I don't know of
18 long-term data beyond 17 years of the TVT-O, but
19 we do have that for TVT. So it's hard to compare
20 the outcomes of a procedure where you have 5-year
21 data and 17-year data. In terms of safety, they
22 have a different set of complications. You don't
23 see groin and thigh pain, and you don't see
24 abscesses in the obturator muscle with a TVT.

25 Q. Doctor, is it your testimony that a

1 17-year study is not sufficient to offer an
2 opinion as to the safety and efficacy of a
3 medical device?

4 MR. ORENT: Objection.

5 A. Again, I think you're misquoting
6 me. I said that we have --

7 Q. I'm asking you this question then.

8 A. No. I think a 17-year study is
9 amazing in terms of longitudinal follow-up, and
10 we have that for TVT. But you asked me that
11 isn't it your opinion that TVT-O is as
12 efficacious as a TVT, and my response was is that
13 I can't tell you that because I have 17-year data
14 for a TVT, and I don't have anything close to
15 that for a TVT-O.

16 Q. So how much data do you need for
17 the TVT-O before you would make that opinion?

18 MR. ORENT: Objection.

19 A. Well, if you're comparing two
20 products, I would think that you would have to
21 have comparative data. To compare the efficacy
22 of one procedure at 5 years to the efficacy of
23 another procedure at 17 years just seems flawed
24 in my case.

25 Q. So are you saying that in order to

1 compare the efficacy of the TVT to the TVT-O we
2 have to wait until the TVT-O has been on the
3 market for 17 years?

4 A. What I'm saying is that I can't
5 tell you --

6 Q. I just want you to answer that
7 question.

8 MR. ORENT: Objection.

9 A. Yes.

10 Q. Okay. Have you ever had done any
11 meta-analyses yourself?

12 A. Not a meta-analyses per se. We
13 have done reviews of the literature when we're
14 doing review papers where we look at the
15 different reviews and we may actually put them in
16 a tabular format. But in terms of doing a
17 statistical analysis pooling the meta-analyses,
18 no.

19 Q. Would you consider yourself
20 qualified to do that?

21 A. Again, my clinical expertise is not
22 in statistics. I would most likely be talking to
23 a statistician to help develop those analyses.

24 Q. Would you agree that a randomized
25 clinical trial is one of the most effective ways

1 to evaluate a medical device?

2 MR. ORENT: Objection.

3 A. I think given its limitations,
4 although there are limitations to it, it is
5 probably considered Level I data comparative to
6 other types of studies.

7 Q. All right.

8 (Whereupon, Deposition Exhibit 13,
9 Effectiveness and complication rates of
10 tension-free vaginal tape-obturator in the
11 treatment of female stress urinary
12 incontinence in a medium- to long-term
13 follow up by Pan-Fen Tan, et al,
14 was marked for identification.)

15 Q. (BY MS. GUILFOYLE) Doctor, I'm
16 going to show you what's been marked as
17 Exhibit 13 for this deposition --

18 A. Thank you.

19 Q. -- and ask you if you've ever seen
20 this article before.

21 A. I believe I have.

22 Q. Was that in fact one of the
23 articles that you relied on in conjunction with
24 forming your opinions?

25 A. Yes.

1 Q. This is a retrospective study,
2 right, that reports on the long-term outcome of
3 the use of TVT-O?

4 A. Okay, I'm looking at a different
5 paper. This is what I was given. This is not a
6 retrospective study.

7 Q. Right, okay. Well, you're familiar
8 with this study, Doctor?

9 A. Yes.

10 Q. You're familiar with the
11 conclusions reached during this meta-analysis?

12 A. I'd have to just look at that
13 briefly again. And what would you like me to --

14 Q. Directing your attention to the
15 conclusion --

16 A. Yes.

17 Q. -- do you see where it says, "The
18 subjective and objective cure rates of stress
19 urinary incontinence were similar among TVT, TOT,
20 and TVT-O in a medium- to long-term follow-up"?

21 A. Yes.

22 Q. Did I read that correctly?

23 A. Yes.

24 Q. And then it says, "The TVT had a
25 higher risk of bladder perforation than TVT-O and

1 a lower risk of groin/thigh pain than TOT, and
2 TVT had a lower risk of vaginal erosion rates
3 than TOT." Did I read that correctly?

4 A. Yes.

5 Q. Do you have any factual evidence
6 that would contradict the findings of this
7 article?

8 MR. ORENT: Objection.

9 A. Again, there are other papers that
10 have a completely different conclusion. When you
11 look at the discussion, they talk a little bit
12 about the limitations of this paper in terms of
13 many of these randomized controlled trials had
14 small numbers and short-term follow-up.

15 Q. If I could just -- what articles
16 are you referring to contradict this, the
17 findings of this article?

18 A. I don't have those off the top of
19 my head, but I have seen articles that talk about
20 different conclusions in terms of long-term
21 outcomes as well as complications, and I'd be
22 happy to provide you those.

23 Q. Okay. Well, before we go off the
24 record -- I guess before we go off the record
25 I'll take a break and I'll have you look at your

1 report and tell me where you have referenced any
2 study that contradicted the findings of this
3 article.

4 A. Okay.

5 MR. ORENT: Well, I'm not sure that
6 that's appropriate to do off the record. I think
7 any question, if you're going to have him do
8 work, that counts against the time.

9 MS. GUILFOYLE: Well, I disagree
10 with that. Maybe we won't get there.

11 (Whereupon, Deposition Exhibit 14,
12 Seven years of objective and subjective
13 outcomes of transobturator vaginal tape:
14 Why do tapes fail, Stavros Athanasiou, et al
15 was marked for identification.)

16 Q. (BY MS. GUILFOYLE) I'm going to
17 show you what's been marked as Exhibit 14,
18 Doctor, and ask you to take a look at that. Have
19 you seen this article before?

20 A. Yes.

21 Q. Okay. That's the seven-year study
22 that you were talking about --

23 A. Yes.

24 Q. -- before, right?

25 Are you familiar with the term KHQ?

1 A. It's a questionnaire that's used as
2 a quality of life measure.

3 Q. Right. That's the King's --

4 A. Health Questionnaire.

5 Q. -- Health Questionnaire. And is
6 that something that you use in conjunction with
7 your patients?

8 A. No, we typically don't. There are
9 a variety of different quality of life measures
10 for both incontinence and prolapse domains. We
11 typically use a thing called the PFDI which is
12 the pelvic floor distress inventory. Different
13 studies use different subjective questionnaires.

14 Q. But you agree that the use of a
15 questionnaire, whether it's the one that you use
16 or something like the KHQ, is an important tool
17 in assessing patient cure rates?

18 A. Well, there's two ways to assess
19 patient cure rates, objective and subjective --

20 Q. Right.

21 A. -- and some of the validated
22 questionnaires are used for subjective
23 assessment, and the King's Health Questionnaire
24 is one of those widely accepted validated
25 questionnaires.

1 Q. Okay. Now, if you look at the
2 conclusion of this seven-year study, Doctor, it
3 says, "The TVT-O procedure provides high
4 objective and subjective long-term efficacy, a
5 clinically meaningful improvement in patient
6 quality of life, and an excellent safety
7 profile." Do you see that?

8 A. Yes.

9 Q. Do you have any evidence that
10 contradicts the findings of this study?

11 A. I think this is what they concluded
12 from their analysis of their patients.

13 Q. This involved 124 consecutive
14 women, right?

15 A. Correct.

16 Q. Do you have any criticisms of this
17 study?

18 A. Well, this is a Level III/Level IV
19 study. So when we talked about the validity of
20 studies going from Level I being a randomized
21 prospective, this is a retrospective study which
22 has no control group, and so it's an
23 observational study.

24 So the quality of the study in
25 speaking of the previous study grades that we

1 talked about, it's in a Level III, Level IV.

2 Q. Okay. But certainly more of a
3 study than what you've done on TVT-O, right?

4 MR. ORENT: Objection.

5 A. Yes.

6 Q. And if you look at the tables
7 reflecting the King's Health Questionnaire
8 results, and it's on page 223.

9 A. Yes.

10 Q. Are those the same types of domains
11 that you use in the questionnaire that you use
12 with your patients?

13 A. The King's Health Questionnaire is
14 more of a psychosocial/emotional type of
15 questionnaire. The PFDI is more of a
16 symptomatic. So they looked at psychosocial
17 aspects as opposed to symptom relief.

18 So this was more how patients
19 perceived their life changed after the procedure
20 as opposed to what was the subjective cure rate
21 of the procedure.

22 Q. But there's no way -- I mean, they
23 can -- both of those would be related, would you
24 agree? Their subjective feelings versus their
25 objective cure rate.

1 MR. ORENT: Objection.

2 A. No. So, again, you're misplacing
3 the text. There's subjective cure rate versus
4 objective cure rate, and there's subjective
5 feelings. So you said, well, there's subjective
6 feelings and there's objective cure rate. There
7 is, but when you assess outcomes or success,
8 you're looking at cure rates or improvement
9 rates, and those can be subjective according to a
10 survey that assesses that or they can be
11 objective compared to testing or documentation.

12 The King's Health Questionnaire
13 does a subjective evaluation of a patient's
14 feelings or impressions towards a procedure and
15 how it impacted various domains of their life
16 psychosocially.

17 A subjective cure rate talks about
18 do you feel like you are improved and did it
19 improve your incontinence.

20 Q. Looking at the King's Health
21 Questionnaire data, and in particular if you want
22 to look at page 221, it showed a statistically
23 significant improvement in all domains. Then
24 furthermore, in terms of clinically relevant
25 improvement, the difference between mean

1 postoperative and preoperative values were over
2 the MICD. Do you know what MICD means?

3 MR. ORENT: Objection.

4 A. Not in this context.

5 Q. Does it mean different things in
6 different contexts?

7 A. No. I don't know what they refer
8 to as MICD here.

9 Q. Okay.

10 A. But --

11 Q. It also says, "There were no major
12 perioperative complications, such as bladder
13 perforation, vessel injuries and obturator
14 hematomas." Did I read that correctly?

15 A. Yes.

16 Q. Do you have any reason to doubt the
17 factual accuracy of the findings in this report?

18 MR. ORENT: Objection.

19 A. No.

20 Q. In this -- staying with that study,
21 I noted that there was no long-term groin pain
22 noted.

23 Do you see the chart that talks
24 about the long-term follow-up?

25 MR. ORENT: Are you talking about

1 the one on 223?

2 MS. GUILFOYLE: Yes.

3 A. That's the King's Health
4 Questionnaire.

5 Q. I feel like I'm missing a page.
6 You can mark this.

7 (Whereupon, Deposition Exhibit 15,
8 Five-year Results of a Randomized Trial
9 Comparing Retropubic and Transobturator
10 Midurethral Slings for Stress Incontinence,
11 Eija Laurikaninen, et al
12 was marked for identification.)

13 Q. (BY MS. GUILFOYLE) Doctor, I'm
14 going to show you what's been marked as
15 Exhibit 15 and ask you whether you've seen this
16 article before.

17 A. I have.

18 Q. You are familiar -- this is a
19 randomized clinical trial, right?

20 A. Yes.

21 Q. And here the results were
22 particularly significant because they were able
23 to test 95 percent of the initial study
24 participants after five years. Do you recall
25 that?

1 A. Yes.

2 Q. And this randomized clinical trial
3 concluded that there was no difference in cure or
4 complication rates between the TVT and the TVT-O;
5 isn't that true?

6 A. Cure rates were similar, and
7 patient satisfaction was similar. I don't see
8 where the complication rate table is. Let's see.

9 Q. I don't know if there's a table on
10 here.

11 A. It does say that they were low with
12 no difference between the groups.

13 Q. And you don't have any reason to
14 doubt the accuracy of the findings of this
15 report, do you?

16 A. No.

17 Q. Do you see the patient satisfaction
18 table which is Table 3?

19 A. Yes.

20 Q. And would you agree that the --
21 that their patient satisfaction rate between the
22 TVT and TVT-O were similar and high?

23 MR. ORENT: Objection.

24 A. Yes, there's no significant
25 difference between the two groups.

1 Q. All right. Did you rely on this
2 study at all in forming your opinions?

3 A. This was one of the studies I
4 reviewed.

5 Q. But did you rely on it in forming
6 your opinions?

7 A. Well, I relied on the entire number
8 of studies that I reviewed not only during this
9 process but also outside of this as part of my
10 clinical practice.

11 Q. Now, in your report you talk about
12 the various different types of slings, like the
13 Monarc, the Delorme. Do you recall that in your
14 report, other slings?

15 A. Yes.

16 Q. And they're all made out of
17 polypropylene mesh, right?

18 A. Yes.

19 Q. And would you offer the same
20 opinion about the safety and efficacy of those
21 slings?

22 MR. ORENT: Objection.

23 A. In what regard?

24 Q. That you're offering -- is your
25 opinion with respect to those slings the same as

1 it is with respect to the TVT-O?

2 MR. ORENT: Objection.

3 A. Well, the anatomic -- the
4 procedural steps as well as the anatomic
5 landmarks and position of the TVT-O is different.
6 But in terms of them both being transobturator
7 slings, they are both transobturator slings. But
8 they are different, so it's hard to say that all
9 of my opinions for TVT-O would apply to
10 transobturator and I didn't have any opinions
11 regarding transobturator for the basis of this
12 report.

13 Q. Mm-hmm. Now, on page 24 of your
14 report and on Figure 5, you talk about the
15 needles that are used in the TVT-O are far more
16 complex than the TOT.

17 A. Yes.

18 Q. Can you just explain what you mean
19 by that?

20 A. I really wish I had the needles
21 here, but in lieu of that, the traditional
22 needles for a transobturator fall within two
23 basic categories. One is a flat C needle which
24 is very one dimensional, and it only has a C on
25 it. And then the other is a slightly more 3D

1 helical needle which comes straight out and has a
2 90 degree curvature to it. Those are both
3 spatially much easier to understand. When we
4 pass needles blindly, we're always taught that
5 you want to try to envision where your needle tip
6 is at all times, and that's a function of the
7 configuration of the needle as well as what its
8 relationship is to the handle. The TVT-O
9 needle -- again I wish I had a sample here -- if
10 you looked at it, it's a much more complex helix,
11 and as a result, it takes more insight and
12 understanding and potentially experience for a
13 surgeon to know where that tip is.

14 Q. Okay.

15 A. And part of the safety profile is
16 if I want to know at all times where my needle
17 tip is, and that was one of the issues I had and
18 one of the issues we discussed in terms of the
19 previous cadaver labs.

20 Q. Okay. Can we take a break?

21 MR. ORENT: Sure.

22 (A break was taken.)

23 Q. (BY MS. GUILFOYLE) Doctor, I'm
24 going to hand back the Tan article to you and ask
25 you if you could to go to page 29. It talks

1 about the prevalence of intraoperative
2 complications. Do you see -- it's actually on
3 the right-hand column.

4 A. The left-hand column.

5 Q. I think the right-hand column.

6 With regard to complications, complication rates.

7 A. I've got "With regard to
8 complication rates, the prevalence of
9 intraoperative bladder perforation" --

10 Q. Oh, yeah, you're right. Right. Do
11 you see that section?

12 A. Yes.

13 Q. Okay. Do you see that the
14 complication rates of intraoperative bladder,
15 perforation, hematoma and void difficulties/
16 urinary retention were significantly lower in the
17 TVT-O group?

18 A. Yes.

19 Q. Do you have any reason to doubt the
20 accuracy of these findings?

21 A. No.

22 Q. And then if you can go to the
23 right-hand column, the first full paragraph. It
24 says, "With regard to complication rates, the
25 reoperation rate was significantly higher in TOT

1 compared with TVT-O."

2 A. Yes.

3 Q. Do you see that? Do you have any
4 reason to doubt those findings?

5 A. No.

6 (Whereupon, Deposition Exhibit 16,
7 Medium-term and long-term outcomes following
8 placement of midurethral slings for stress
9 urinary incontinence: a systematic review
10 and metaanalysis, Giovanni A.
11 Tommaselli, et al, was marked
12 for identification.)

13 Q. (BY MS. GUILFOYLE) I'm going to
14 show you what's been marked as Exhibit 16 and ask
15 you whether or not you've seen that article?

16 A. Yes.

17 Q. Is this an article that you
18 reviewed in connection with your forming your
19 opinions in this case?

20 A. Yes.

21 Q. Do you agree with the conclusions
22 reached in the Tommaselli argument? I mean
23 Tommaselli paper.

24 MR. ORENT: Objection. What do you
25 mean by agree?

1 Q. Do you agree with the findings?

2 MR. ORENT: Objection to form.

3 Q. Do you have any reason to doubt the
4 accuracy of the findings?

5 A. That the transobturator sling is
6 associated with a lower subjective cure rate than
7 the retropubic sling.

8 Q. No, I was going to direct you
9 somewhere else.

10 A. Okay, 'cause that was their
11 conclusion.

12 Q. That may be one of their
13 conclusions.

14 A. Well, that was the only conclusion
15 that's in the abstract in the front.

16 Q. Okay. Well, let me direct you to
17 another page then, Doctor.

18 A. Sure.

19 Q. Did you see in the Tommaselli
20 argument -- paper that vaginal injuries were more
21 common with the TOT than the TVT-O?

22 A. Could you direct me to the specific
23 area?

24 Q. Sure. On page -- page 7.

25 A. I don't even have page numbers on

1 mine.

2 MR. ORENT: Is this the page with
3 Figure 3?

4 MS. GUILFOYLE: Figure 2.

5 A. 7.

6 Q. So it's on the left-hand column.

7 First it says, "No significant difference was
8 observed in complications between the TVT-O and
9 the TOT."

10 MR. ORENT: Objection, misstates
11 the document.

12 Q. And then it continues on and says,
13 "Vaginal injuries were more common with TOT than
14 the TVT-O." Did I read that correctly?

15 A. Yes.

16 Q. And then if you can go to -- well,
17 do you have any reason to doubt the accuracy of
18 those findings?

19 A. Of the statements you read?

20 Q. Yes.

21 A. No.

22 Q. Based on your experience, do you
23 have any reason to doubt the accuracy of the
24 findings in the Tommaselli report --

25 MR. ORENT: Objection.

1 Q. -- paper?

2 A. Are you talking about my experience
3 in terms --

4 Q. With the 30 to 50 people that --

5 A. Oh, I was going to ask, just in
6 terms of my patients that I've seen?

7 Q. Right.

8 A. No.

9 Q. Now, one of your other opinions
10 that you have given is that the TVT-O has an
11 increased pain complication component --

12 A. Yes.

13 Q. -- is that fair to say?

14 A. Yes.

15 Q. And what exactly is your opinion in
16 that regard?

17 A. Groin pain and vaginal pain is
18 higher in TVT-O compared to retropubic slings
19 which is what my mainstay of treatment is for my
20 patients.

21 Q. And what studies do you rely upon
22 to support that opinion?

23 A. All the studies that we've talked
24 about. In addition -- that I was asked to
25 review. In addition to the previous studies that

1 I looked at as part of my clinical experience and
2 responsibilities and in terms of my experience
3 over the last 15 years.

4 Q. Well, when you say all the studies
5 that you were asked to review, do you mean here
6 today at the deposition?

7 A. Yes, many of them will talk
8 about --

9 Q. Well, can you just first answer
10 that question?

11 A. Yes, yes.

12 Q. And then the other studies that you
13 were asked to review, you're referring to ones
14 that were given to you by plaintiffs counsel?

15 MR. ORENT: Objection, misstates
16 his testimony.

17 Q. You talked about three sources of
18 articles.

19 A. Correct, the studies that you
20 presented to me today --

21 Q. Right.

22 A. -- the studies that I was asked to
23 review as part of this that were on my thumb
24 drive --

25 Q. Right.

1 A. -- and the other studies and
2 experiences that I've had as part of my clinical
3 practice and my research responsibilities and
4 lecturing responsibilities around the country.

5 Q. And do you have as you sit here
6 today, Doctor, 'cause I don't know that I saw it
7 in your report, any particular studies that you
8 rely on to support the position that the use of
9 TVT-O is more likely to result in pain -- groin
10 pain?

11 A. Compared to retropubic slings?

12 Q. Right. Other than on a short-term
13 basis.

14 A. Yeah. I mean, we can use the study
15 that you just gave me where if you look at some
16 of the sections and complications that you didn't
17 read, it actually says that groin pain and thigh
18 pain was more common in the TVT-O groups.

19 In addition --

20 Q. Short term or long term, Doctor?

21 A. Well, again, they don't necessarily
22 discriminate between the two, and you would have
23 to go back to all of the randomized controlled
24 trials that they looked at and talk about long
25 term and short term.

1 The papers that we've seen, and
2 again I can bring those papers out, they've all
3 shown some level of long-term complications.
4 I've seen it in my clinical practice where
5 patients have not had significant groin pain and
6 then three years or four years later they have.

7 And then lastly I would tell you
8 that we wrote a paper in 1998 which was one of
9 the earliest papers about mesh complication about
10 sacral colpopexy, and what we found is when
11 you're dealing with a permanent implant which is
12 there permanently, there's no real statute of
13 limitations on when complications can occur. So
14 erosions, exposure, contraction, pain can occur
15 any time.

16 So when you're showing me papers
17 that have six-month, three-month, two-year,
18 five-year data, I would tell you that those
19 complications aren't necessarily absolute in the
20 sense that other complications unique to mesh
21 use, which is a permanent material, can happen
22 beyond that time frame, and that's what I've seen
23 in my clinical practice.

24 Q. Sure. And you're talking about --
25 but you can find all of those, erosion, pain with

1 respect to any product that's implanted in the
2 body; isn't that true?

3 MR. ORENT: Objection.

4 A. But, again, you specifically asked
5 me about groin pain, and I don't see groin pain
6 when I do a retropubic sling procedure.

7 Q. You've never seen groin pain when
8 you've used a retropubic sling procedure?

9 A. Not to my recollection because the
10 mesh doesn't pass in the groin area.

11 Q. Okay. And of the 30 to 50 patients
12 that you have dealt with personally, how many
13 have long-term groin pain that you attribute
14 solely to the use of the sling, the TVT sling?

15 MR. ORENT: Objection.

16 A. The complications that I was taking
17 care of?

18 Q. Yes.

19 A. The vast majority of them had
20 either vaginal or groin pain.

21 Q. But I'm talking about a number.
22 You said you treated 30 to 50. What percentage
23 of the 30 to 50 have you diagnosed with long-term
24 groin pain that you attribute solely to the use
25 of the TVT-O?

1 MR. ORENT: Objection.

2 A. And are we separating the vaginal
3 pain, just groin pain.

4 Q. Yes, first groin pain.

5 A. I would probably say about 10
6 percent, 15 percent.

7 Q. And how is it that you come up with
8 that number?

9 A. To my recollection about what we
10 talked to them about and what the treatments are.
11 I had talked to you about the fact that if they
12 had groin discomfort, we talked to them about
13 removing that groin portion of the mesh.

14 And if you look at how many we've
15 done, it's been a small handful. So out of the
16 30 to 50, 10 to 15 percent had that type of
17 symptoms, a small handful opted to have surgical
18 revision and a small number which we talked about
19 opted to either have injections or physical
20 therapy or do nothing.

21 Q. So that's under ten people that
22 you've actually physically treated?

23 MR. ORENT: Objection.

24 A. Surgically, in terms of removing
25 the groin portion of TVT-O.

1 Q. But I thought your testimony before
2 was that the 30 to 50 were people that you
3 actually evaluated for compli -- and treated for
4 complications that you attribute to the TVT-O but
5 that you did not necessarily perform surgery in
6 all cases?

7 MR. ORENT: Objection.

8 A. Correct, so I told you that
9 probably about 10 to 15 percent of those patients
10 had chronic long-term or long -- delayed onset
11 groin pain --

12 Q. Right.

13 A. -- out of the 30 to 50 for mesh
14 complications.

15 Q. Right, under ten. Under ten then.

16 A. Yes.

17 Q. And are you aware of any other
18 procedures, say the TOT, where people have groin
19 pain that they associate with the procedure?

20 A. Yes.

21 Q. And isn't it true, Doctor, that if
22 there were, say, an infection on the needles that
23 were inserted that you could get groin pain as
24 well?

25 A. Are you talking short term or long

1 term.

2 Q. Well, initially short term. You
3 certainly could get short term.

4 A. Yes.

5 Q. Right. And could that result in
6 long-term complications, Doctor?

7 MR. ORENT: Objection.

8 Q. If untreated.

9 A. If we are talking about the needle
10 being infected, typically that would show up in
11 the short term, not as opposed to in the long
12 term because then that infection would be
13 probably of a different etiology.

14 Q. So you're saying it's not possible
15 to have a long-term infection of the groin as a
16 result of that?

17 MR. ORENT: Objection.

18 A. Again, if you tell me what long
19 term means. If you told me two years from the
20 time of the initial implant, I would say probably
21 not. That's like having a UTI for two years that
22 was never treated. If you told me that, you
23 know, it was three months, four months and that's
24 your definition of long term, you know, I think
25 an infection that was present at the time of

1 surgery could fester for three to four months,
2 but it wouldn't show up three years after putting
3 that mesh in.

4 Q. So what percentage of the patients,
5 the 30 to 50 patients that you treated that have
6 groin pain, have had a delayed onset of groin
7 pain?

8 A. The vast majority would have
9 typically delayed onset. I mean, there was --
10 probably half had delayed onset and half had
11 onset fairly close to the surgery, but there was
12 a delay in diagnosis. It was felt that their
13 pain was due to positional issues. Oh, it will
14 go away. You know, you didn't take proper pain
15 medication, maybe you were too active. So there
16 was a reason to explain away the pain such that
17 it was not diagnosed until it was persistent a
18 year or two years later.

19 Q. Are there other causes of groin
20 pain when the TVT-O is used short of there being
21 a problem with the product itself in your
22 opinion?

23 A. Short term or long term?

24 Q. Both.

25 A. Clearly I think there are some

1 positional issues that depend maybe on the length
2 of the surgery and how the patient was positioned
3 and how that pain manifests itself.

4 When I talk about groin pain
5 related to the mesh, it's typically exactly what
6 we talked about, that when you touch the area of
7 the mesh and where the mesh has been there's pain
8 or tenderness.

9 (Whereupon, Deposition Exhibit 17,
10 Two Routes of Transobturator tape procedures
11 in stress urinary incontinence: A
12 meta-analysis with direct and indirect
13 comparison of randomized trials,
14 Pallavi M. Latthe, et al
15 was marked for identification.)

16 Q. (BY MS. GUILFOYLE) All right. I'm
17 going to show you No. 17 --

18 A. Thank you.

19 Q. -- and ask you, Doctor, if you've
20 seen that.

21 A. Excuse me, one second. I
22 apologize.

23 (Discussion off the record.)

24 Q. Are you familiar with this study,
25 Doctor?

1 A. I don't think I've seen this study.

2 Q. Okay. I direct your attention to
3 the conclusion. "The evidence for the equivalent
4 effectiveness of TOT and TVT-O when compared with
5 each other is established over the short term.
6 Bladder injuries and voiding difficulties seem to
7 be less with inside-out tapes on direct
8 comparison." Do you have any reason to doubt the
9 findings of this study?

10 A. Again, I haven't had --

11 MR. ORENT: Objection.

12 A. -- the chance to review this in
13 detail. I've just quickly seen that they looked
14 at six months of data, and they're basically
15 saying over the short term. I have no reason to
16 doubt their conclusions, but whether or not there
17 is scientific validity and what they're analytics
18 and study design were, I can't comment on that.

19 Q. Are you aware of any studies that
20 talk about long-term outcomes using the Burch
21 procedure?

22 A. I am aware of studies. I couldn't
23 quote them off the top of my head, but we do have
24 studies that we referenced early on.

25 Q. Can you mark this, please?

1 (Whereupon, Deposition Exhibit 18,
2 Long-Term Results of Burch Colposuspension,
3 Fuat Demirci, et al
4 was marked for identification.)

5 Q. (BY MS. GUILFOYLE) Doctor, do you
6 recognize what's been marked as Exhibit 18?

7 A. I don't think I have seen this
8 study.

9 Q. I direct your attention to the
10 results. "The study included 220 women of whom
11 155 (group II) had undergone a Burch
12 colposuspension procedure three to six years
13 earlier and were evaluated retrospectively. The
14 remaining group (group I) had undergone a Burch
15 colposuspension procedure one to two years
16 earlier and were evaluated prospectively." So
17 they used both a prospective and a retrospective
18 group.

19 A. Yes.

20 Q. So at the end -- on the last page
21 it talks about -- not the last. Yeah, the page
22 before the list of resources. "The present study
23 has shown that a previous incontinence operation
24 impairs results of further incontinence surgery."
25 Do you agree with that?

1 MR. ORENT: Objection.

2 A. In terms of their study conclusion
3 or that that's true?

4 Q. That that's true.

5 A. I think it really depends on what
6 the previous incontinence surgery was, who
7 operated on them and what the follow-up study is.

8 I mean, one of the things we like
9 about slings is that they make good what we call
10 salvage operations, and sometimes the success
11 rate of the secondary procedure can be as high,
12 if not higher, than the initial procedure, but
13 again, their quote is, "The present study has
14 shown that a previous incontinence operation
15 impairs the results of further incontinence
16 surgery," and I can only assume that their
17 conclusion is true, although I haven't had a
18 chance to look at their study methodology.

19 Q. Well, have you experienced that in
20 your own practice, Doctor?

21 A. We do tell patients that oftentimes
22 if you have a second or third incontinence or
23 prolapse procedure your risk of the procedure and
24 the success rates of the procedure may be
25 small -- lower.

1 Assuming that the reason they
2 failed is because they may have other anatomic
3 variants as well as the fact that there might be
4 it scarring and other -- and they're older. So
5 there is that thing to consider. But whether we
6 found that clinically, I haven't studied that
7 specifically in my own patient population.

8 Q. So that's not part of your opinion?

9 MR. ORENT: Objection.

10 Q. Correct, Doctor?

11 A. Part of my opinion?

12 Q. It is not part of your opinion?

13 MR. ORENT: Objection.

14 A. I didn't have any opinion to that
15 in my report.

16 Q. Okay. And then it also indicates
17 that suspension sutures are responsible for groin
18 or suprapubic pain.

19 Have you ever encountered that when
20 you used the Burch procedure, Doctor?

21 A. We have had suprapubic pain.
22 Whether or not that was short term or long term
23 is difficult for me to say 'cause I don't have
24 the details and those procedures were done 15
25 years ago.

1 As far as groin pain, I don't
2 recollect a patient that we did the Burch with
3 that had groin pain, but the groin pain may be
4 related to positional issues, but I don't
5 recollect one of our patients that we did that
6 had a significant or sustained groin pain issue.

7 Q. Were you aware of those statistics
8 within the medical community even if you haven't
9 encountered it as a treating physician?

10 A. Again, this paper talks about it,
11 and I would have to go look at the data in terms
12 of groin pain with Burch colposuspensions, but I
13 haven't seen significant mention of that in my
14 review in the past.

15 Q. Okay. Have you seen any studies
16 talking about the connection between dyspareunia
17 and Burch colposuspensions?

18 A. I have in the past, yes.

19 Q. Well, when you say you've seen it
20 in the past, you don't have any reason to believe
21 that if a Burch procedure was performed today
22 that there wouldn't be those same potential risks
23 of dyspareunia, right?

24 MR. ORENT: Objection.

25 A. No, but I was saying that in the

1 past when I was looking at the Burch procedure I
2 have seen those studies.

3 Q. Okay. Are there any other
4 particular studies, Doctor, or any facts that you
5 rely on that we haven't talked about today to
6 support your opinions?

7 A. No. I mean, I think we haven't
8 specifically gone through every study that I've
9 looked at, but you have a list of the studies in
10 terms of what I specifically looked at for this
11 case as well as other studies outside of that
12 list which I look at for my everyday practice in
13 counseling of patients.

14 Q. Okay. You haven't -- other than
15 that catheter, you haven't designed any medical
16 devices, have you?

17 A. Not that I was -- I would say that
18 I was significantly involved with. I've provided
19 design feedback for a variety of different
20 products --

21 Q. Right.

22 A. -- but not that I would say I was
23 materially involved with.

24 Q. So we've looked at a number of
25 studies that have talked about the risk of

1 complication with TVT-O versus TVT in particular,
2 but one of your opinions is that the TVT-O has an
3 unacceptably high rate of chronic pain. Is that
4 based solely on the groin issue that you
5 testified about earlier?

6 A. That and dyspareunia which we
7 talked about.

8 Q. So when you use pelvic pain, you're
9 referring to dyspareunia?

10 A. Well, pelvic pain I talk about more
11 in terms of a global description. They can have
12 chronic pelvic pain, and it can be worsened with
13 dyspareunia, or they can have dyspareunia which
14 is more acute and incidental, but many times
15 they're used interchangeably.

16 Q. What evidence do you have that
17 Ethicon rushed to market the TVT-O product?

18 A. Well, again, comparatively
19 speaking, there's internal documents where they
20 said that we have -- you know, the production
21 development phase was suppose to be 24 months,
22 and then they patted themselves on the back in
23 the sense that we did it in nine months with
24 limited resources. So that's a fairly quick
25 development phase.

1 In addition, there was some
2 internal documentation which talked about that
3 there is an urgency to get this product out
4 because of competitive pressures and the fact
5 that there was erosion of market share of the
6 TOT -- of the TVT product of Gynecare because of
7 the TOT.

8 Q. Now, Doctor, you -- I think you
9 testified you reviewed approximately or were
10 given access to approximately 2,000 pages of
11 Ethicon documents; is that correct?

12 A. If not more, yes.

13 Q. Okay. You are not, or are you
14 testifying that you have reviewed all the Ethicon
15 documents relative to the development and
16 marketing of the TVT-O?

17 A. No, I'm only testifying that I
18 reviewed the ones that I was provided.

19 Q. Okay. And that's what forms the
20 basis of your opinion?

21 A. Yes.

22 Q. What about the opinion that Ethicon
23 marketed the TVT-O indiscriminately to all
24 physicians? What's the basis for that opinion?

25 A. Well, I think a few things. One

1 is, again, I did a lot of training for Ethicon
2 during that time frame, and if you looked at some
3 of the doctors who attended the cadaver labs, the
4 lectures and our surgical preceptorships, they
5 clearly weren't qualified to do some of these
6 procedures.

7 In addition, in the IFUs which
8 bothered me, they basically made cystoscopy
9 voluntary and at the discretion of the physician
10 which I had a problem with and I voiced it to
11 Ethicon because cystoscopy is a very basic and
12 integral procedure which is performed by doctors
13 who do incontinence work all the time.

14 Now, in the IFU for TVT, cystoscopy
15 is actually recommended and almost required as
16 part of that IFU, whereas in TOT or TVT-O it was
17 recommended to be at the discretion of which
18 really made it appropriate or applicable to a
19 wide range of physicians who never did
20 cystoscopy.

21 Now, if you're not doing cystoscopy
22 and you don't know how to look inside the
23 bladder, I'm not sure if you should be putting
24 needles into the pelvis and meshes in the area of
25 the bladder.

1 Q. What evidence do you have, Doctor,
2 that any doctors who were unqualified or not able
3 to do cystoscopies actually used the TVT-O?

4 A. I wouldn't be able to tell you a
5 number on that.

6 Q. Do you have any information on
7 that?

8 A. I had some doctors who came through
9 my preceptorship who said we don't do cystoscopy
10 and what would you recommend. And, again, it was
11 a time where we could share our personal
12 experiences, and I was pretty clear about the
13 fact that if you don't do cystoscopy I would not
14 do this procedure. And if you are interested in
15 doing this procedure, the first thing I would do
16 is learn how to do cystoscopy.

17 Q. Right. But you don't have any
18 evidence do you, Doctor, that those doctors that
19 you talked about during your preceptorship didn't
20 go back and get trained on how to do
21 cystoscopies, do you?

22 A. I do not.

23 Q. Let's just take one break.

24 (A break was taken.)

25 Q. (BY MS. GUILFOYLE) Doctor, the

1 people that you were training to use the Ethicon
2 products such as the TVT-O are surgeons, correct?

3 A. They're gynecologists.

4 Q. They don't have to be surgeons?

5 A. Well, gynecologists are surgeons --

6 Q. Surgeons, right.

7 A. -- but surgeons aren't all
8 gynecologists. All surgeons aren't
9 gynecologists.

10 Q. But they're gynecological surgeons.

11 A. Yes.

12 Q. And they've had a lot of training
13 through medical school and residency and practice
14 before they even come to go to a like
15 preceptorship or learn about a TVT-O product,
16 correct?

17 A. Can you clarify what training
18 means?

19 Q. Sure. They go through the same
20 type of training that you do. They see a lot of
21 patients, they perform a lot of surgeries, they
22 are trained in medical school, they are trained
23 by their supervisors at the hospitals, correct?

24 MR. ORENT: Objection.

25 A. So many of them have had that

1 requisite training for medical school and
2 residency, but many of them were not doing
3 urologic or urogynecologic surgery.

4 So my training where I was trained
5 in a variety of different urogynecological
6 procedures is very different than theirs. Some
7 of them were coming in to be trained on a
8 incontinence procedure or a sling procedure and
9 had never done an incontinence procedure. So
10 their training -- yes, they were trained to do
11 routine gynecologic procedures which typically
12 are hysterectomies and basic laparoscopies and
13 tubal ligations. But did they have specific
14 training coming in of doing incontinence
15 procedures like Burchs or slings or other slings
16 and did they have anatomy of the newer relevant
17 spaces, I can tell you that many of them didn't.

18 Q. Okay. But your goal was not, and
19 your job, you did not see your job as to teach
20 them to be surgeons, correct?

21 MR. ORENT: Objection.

22 A. My job was to teach with them or
23 share with them how to do this specific surgical
24 procedure.

25 Q. Right, because they're trained to

1 be surgeons elsewhere and are credentialed to be
2 surgeons by the hospitals where they have
3 privileges; isn't that true?

4 MR. ORENT: Objection.

5 A. Again, I had no specific knowledge
6 of their credentialing or what procedure they did
7 in the past, and I was never given that
8 information by Gynecare or almost any other
9 company I taught for.

10 In the course of having
11 conversations and discussions, we would ask, you
12 know, what procedures have you done, what
13 experience have you done so that we could better
14 tailor our education for them when they were with
15 us.

16 Q. Okay. I don't have anything else.

17 A. Thank you.

18 MR. ORENT: I have just a couple of
19 follow-up questions.

20

21 EXAMINATION

22 BY MR. ORENT:

23 Q. Doctor, thank you very much for
24 your testimony today. I want to turn your
25 attention to Exhibit No. 5. You recognize and

1 have discussed this as the 2014 position
2 statement on mesh midurethral slings for stress
3 urinary incontinence from the American
4 Urogynecological Society; is that correct?

5 A. Yes.

6 Q. Okay. And, Doctor, I want to first
7 focus on, starting on page 2. You were asked a
8 question about the monofilament polypropylene
9 mesh midurethral sling is the most extensively
10 studied anti-incontinence procedure in history.
11 Do you remember being asked questions about that?

12 A. Yes.

13 Q. Doctor, has anyone ever claimed
14 that the TVT-O is the most extensively studied
15 anti-incontinence procedure in history?

16 MR. GUILFOYLE: Objection.

17 A. No.

18 Q. And is it in fact the most
19 extensively studied anti-incontinence procedure
20 in history?

21 MS. GUILFOYLE: Objection.

22 A. No.

23 Q. And this piece mentions 2,000
24 publications in the scientific literature
25 describing MUS and the treatment of SUI.

1 Doctor, are there 2,000 studies
2 describing TVT-O?

3 MS. GUILFOYLE: Objection.

4 A. No.

5 Q. And, Doctor, if you see here,
6 Full-length -- on paragraph number 3, Full-length
7 midurethral slings, both retropubic and
8 transobturator, have been extensively studied and
9 are safe and effective. Relative to other
10 treatment options they remain the leading
11 treatment option and current gold standard for
12 stress urinary incontinence. Do you see that
13 sentence?

14 A. Yes.

15 Q. And then it follows up with that,
16 "Over 3 million midurethral slings have been
17 placed worldwide and a recent survey indicates
18 that these procedures are used by greater than 99
19 percent of AUGS members." And that lists a
20 footnote 14, do you see that?

21 A. Yes.

22 Q. And, Doctor, I'm going to turn now
23 to Footnotes 13 and 14. Number 14 is the study
24 on the impact of the FDA transvaginal mesh safety
25 updates on AUGS members' use of synthetic mesh

1 and biological grafts in reconstructive surgery;
2 is that correct?

3 A. Yes.

4 Q. The aim of this study was
5 explicitly to determine whether or not the FDA's
6 statements changed usage; is that correct?

7 MS. GUILFOYLE: Objection.

8 A. Yes.

9 Q. It had nothing to do with a gauge
10 on what percentage. It was not intended to
11 determine what percentage of AUGS members used
12 polypropylene midurethral slings, correct?

13 MS. GUILFOYLE: Objection.

14 A. Yes.

15 Q. And the response rate was
16 relatively low for that particular survey; is
17 that correct?

18 MS. GUILFOYLE: Objection.

19 A. Yes.

20 Q. And when you look at a study, you
21 look at things like response rate are pretty
22 important factors, correct?

23 MS. GUILFOYLE: Objection.

24 A. Yes.

25 Q. And this statement was written by

1 Charles Nager, N-A-G-E-R, Paul Tulikangas and
2 Dennis Miller from AUGS and Eric Rovner and
3 Howard Goldman from SUFU, S-U-F-U.

4 Doctor, to your knowledge, does
5 Dr. Miller have associations -- does he own a
6 patent to polypropylene mesh devices?

7 MS. GUILFOYLE: Objection.

8 A. Yes.

9 Q. And is that disclosed anywhere in
10 here?

11 MS. GUILFOYLE: Objection.

12 A. No.

13 Q. And, Doctor, do you know does
14 Dr. Goldman have associations with AMS or other
15 manufacturers?

16 MS. GUILFOYLE: Objection.

17 A. Yes.

18 Q. Okay. Is that disclosed anywhere
19 in here?

20 A. No.

21 Q. Doctor, as a professional, do you
22 think that facts like conflict of interest are
23 important things to disclose?

24 A. Yes.

25 MS. GUILFOYLE: Objection.

1 Q. Doctor, you were shown Exhibit 17,
2 which was an article that you had not previously
3 seen before. It's from the BJU International out
4 of the United Kingdom. Do you remember being
5 shown this article?

6 A. Yes.

7 Q. Doctor, there is a groin/thigh pain
8 TVT-O odds ratio of 8.05 which is between 3.78
9 and 17.16. Can you tell us what an odds ratio of
10 8.05 means?

11 MS. GUILFOYLE: Objection.

12 A. Well, it essentially means that
13 there's a eight times higher risk or odds that
14 one procedure might actually have a specific
15 complication or occurrence compared to another.

16 So if you have an odds ratio of
17 one, they're basically equivalent. If you have
18 an odds ratio of a positive number, it means that
19 one procedure has a higher odds of having that
20 complication or outcome.

21 And in this case, eight would mean
22 that it would be eight times higher, and the
23 variation on that would be between 3 and 17. So
24 in some studies, it was 17 times higher of TVT-O
25 versus its comparative surgical procedure.

1 Q. And, Doctor, is an eight times odds
2 ratio, is that significant to you as a treating
3 physician --

4 MS. GUILFOYLE: Objection.

5 Q. -- as a doctor?

6 MS. GUILFOYLE: Objection.

7 A. Yes.

8 Q. And why is that significant?

9 A. Well, again, based on its review of
10 the literature, it shows how much more frequently
11 is it with one procedure versus another. And
12 when you're looking at complications, numbers
13 that are five, six, seven, eight, ten times are
14 relevant and significant.

15 Q. Okay. Thank you very much, Doctor,
16 I have no further questions.

17 MS. GUILFOYLE: I just have a
18 couple of questions.

19

20 FURTHER EXAMINATION

21 BY MS. GUILFOYLE:

22 Q. Doctor, I just have one question
23 about the position statement --

24 A. Sure.

25 Q. -- on mesh. You were asked about

1 number 2, the monofilament polypropylene mesh MUS
2 is the most extensively studied incontinence
3 procedure in history. Do you recall answering
4 questions about that from Mr. Orent?

5 A. Yes.

6 Q. And I guess my question is, the
7 monofilament polypropylene mesh that is used
8 in -- that is referred to here is the same
9 monofilament polypropylene mesh that's used in
10 the TVT-O; isn't that true?

11 MR. ORENT: Objection.

12 A. Yes.

13 Q. Okay. I don't have anything else.

14 (Deposition concluded at 4:52 p.m.)

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1 C E R T I F I C A T E

2 I, Maryellen Coughlin, RPR/CRR and
3 notary public in the Commonwealth of
4 Massachusetts, do hereby certify that the
5 foregoing is a true and accurate transcript of
6 my stenographic notes of the deposition of
7 NEERAJ KOHLI, M.D., who appeared before me,
8 satisfactorily identified himself, and was by me
9 duly sworn, taken at the place and on the date
10 hereinbefore set forth.

11 I further certify that I am neither
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ACKNOWLEDGMENT OF DEPONENT

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DATE

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_____ day of _____, 20____.

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